Operator's Manual

3100A

High Frequency Oscillatory Ventilator

Part Number 767124-101 *Revision L* *© 2005 VIASYS Respiratory Care Inc.*

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Revision History

Date	Revision	Changes
February 1991	A	Initial Release
May 1991	B	Corrected page numbers in TOC. Corrected figure references. Patient Circuit Assy. modified. Warning added. Instructions for changing the patient circuit added. Intervention chart added.
June 1991	C	Changed filter replacement interval to every 500 hours. Changed part number of filter element.
July 1991	D	Updated labeling for disposable components. Update picture for new filters. Change support arm to cradle rod. Update picture to show cradle rod. Add cradle rod to installation. Corrected missing filter, changed warning. Repaginated. Correct adjustments for new patient circuit. Added new patient circuit to performance checks. Added P/N for Humidifier tubing.
August 1991	E	Corrected patient circuit setup limits. Update label for new setup limits. Changed power requirements to reflect circuit breaker change.
November 1991	F	Removed IEC 601-1 and BSI approval. Changed 50 to 56 in step h. Corrected description of filter elements to pack of 10.
May 1995	H	Added pediatric Indications for Use. Updated RI warning. Corrected ET tube size references. Pediatric graph added. Corrected humidifier reference. Corrected gas flow reference. Added color coding. Corrected pre-use cleaning instructions. Added pediatric clinical guidelines. Reformatted Warnings & Precautions.
September 1996	J	Removed City of LA label. Added new power supply. Updated control package DC Tech Support. Power supply procedure. Updated step 7-g of start-up procedure.
March 2002	K	Reformatted to conform with Critical Care Division Operator Manual format. Re-Ordered Chapters. Revised page numbering. Added Checklist Label and 6000 hour Driver Replacement label. Added air cooling inlet flow for 3ohm driver. Added pneumatic block diagram with PR7. Updated pneumatic diagram with PR1 to current revision. Added reference to 6000 and 12000 hour scheduled maintenance. Added P/N s for flexible patient circuit. In-line suction systems addressed. Changed all references to BIAS PRESSURE to read MEAN AIRWAY PRESSURE. Changed usage of "neonate" to read "patient" where appropriate. Added front matter to conform with Critical Care standards. Modified suctioning guidelines.
April 2006	L	Revised for ECR 61201. Added scheduled maintenance for Power Module Assy.

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Warranty

3100A ventilation systems (the equipment) are warranted to be free from defects in material and workmanship and to meet the published specifications for one (1) year from the date of delivery of the equipment to the original purchaser.

Exclusions:

VIASYS Healthcare, Critical Care Division (the company) shall not be responsible for any damage or failure caused indirectly or directly by operation of the equipment outside of the allowable electrical, temperature and other environmental limits specified by the company, or by deficiencies in customer-supplied services or supplies.

The equipment is supplied with some components and accessories, which by their nature are not intended to, and will not, function for one year. If any such component or accessory manufactured by the company and supplied with the equipment fails to give reasonable service for a reasonable period of time, the company will, at its discretion, replace or repair such component or accessory. What constitutes reasonable service and a reasonable period of time shall be determined by the company after the company is in possession of all the facts concerning said component or accessory, and after said component or accessory has been returned to the company with transportation charges prepaid.

The company makes no warranty concerning components or accessories not manufactured by or for the company.

The company shall be released from all obligations under this warranty in the event that repairs or modifications to the equipment are made by persons other than personnel trained and/or authorized by the company. Any authorization by the company for repair or alteration by the Buyer must be in writing to prevent voiding of the warranty. In no event shall the company be liable to the Buyer for loss of profits, loss of use, consequential damage or damages of any kind based upon a claim for breach of warranty, other than the purchase price of any defective product covered hereunder.

Exclusive Remedy:

The liability of VIASYS Healthcare, Critical Care Division (the company) under this warranty is limited to replacing, repairing or issuing credit, at the discretion of the company, for parts that become defective or fail to meet published specifications during the warranty period. The company will not be liable under this warranty unless (A) the company is promptly notified in writing by Buyer upon discovery of defects or failure to meet published specifications; (B) the defective unit or part is returned to the company, transportation charges prepaid by Buyer; (C) the defective unit or part is received by the company for adjustment no later than four weeks following the last day of the warranty period; and (D) the company's examination of such unit or part shall disclose, to its satisfaction, that such defects or failures have not been caused by misuse, neglect, improper installation, unauthorized repair, alteration or accident.

Disclaimers

VIASYS Healthcare warranties as herein and above set forth shall not be enlarged, diminished or affected by, and no obligation or liability shall arise or grow out of the rendering of technical advice or service by VIASYS Healthcare or its agents in connection with the Buyer's order of the products furnished hereunder.

The foregoing is in lieu of any warranty, expressed or implied, including, without limitation, any warranty of merchantability, except as to title, and can be amended only in writing by a duly authorized representative of VIASYS Healthcare, Critical Care Division.

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EMC Notice

This equipment generates, uses, and can radiate radio frequency energy. If not installed and used in accordance with the instructions in this manual, electromagnetic interference may result. The equipment has been tested and found to comply with the limits set forth in EN60601-1-2 for Medical Products. These limits provide reasonable protection against electromagnetic interference when operated in the intended use environments described in this manual.

MRI Notice

This equipment contains electromagnetic components whose operation can be affected by intense electromagnetic fields.

Do not operate the ventilator in an MRI environment or in the vicinity of high-frequency surgical diathermy equipment, defibrillators, or shortwave therapy equipment. Electromagnetic interference could disrupt the operation of the ventilator.

Intended Use Notice

The SensorMedics 3100A High Frequency Oscillatory Ventilator (HFOV) is indicated for ventilatory support and treatment of respiratory failure and barotrauma in neonates. The specific patient conditions, which the HFOV is intended to treat, are respiratory distress syndrome (RDS) or respiratory failure caused by pulmonary interstitial emphysema (PIE) or air leak (AL).

The SensorMedics 3100/3100A is also indicated for use in the ventilatory support and treatment of selected pediatric patients who, in the opinion of their physician, are failing on conventional ventilation. Patient size and other factors are important in the selection of patients to be treated using this ventilator.

The SensorMedics 3100A Oscillatory Ventilator has no specific contraindications.

Restrictions

Federal law restricts the sale of this device except by or on order of a physician.

Declaration of Conformity Notice

This medical equipment complies with the Medical Device Directive, 93/42/EEC, and the following Technical Standards, to which Conformity is declared:

CE
0086

EN60601-1
EN60601-1-2

The Manufacturer's Quality System is certified to:

ISO 9001
EN 46001

EU Notified Body:

National Standards Institute of Ireland (NSAI)

Type of Equipment: Medical Equipment, Lung Ventilator

Trade names: 3100 and 3100A

If you have a question regarding the Declaration of Conformity for this product, please contact SensorMedics Corporation or VIASYS Healthcare, Critical Care Division.

IEC Classification

- The 3100A HFOV ventilator is suitable for use in institutional environments.
- Ordinary equipment, not protected against the ingress of liquids.
- Not protected/not suitable for use in the presence of flammable anesthetic gases.
- Class 1, Type B Equipment.

Safety Information

Please review the following safety information prior to operating the ventilator. It lists information pertinent to the safe operation of the ventilator. Attempting to operate the ventilator without fully understanding its features and functions may result in unsafe operating conditions.

If you have a question regarding the installation, set up, operation, or maintenance of the ventilator, contact Technical Support as shown in Appendix A Contact & Ordering Information.

Adverse Effects

In the pediatric randomized trial, adverse effects identified were lung overdistention, air leak, and hypotension. There were no statistical differences in any of the adverse effects as compared to those reported in the conventionally treated patients with the exception of hypotension. The HFOV treated group had a few (but statistically significant) more frequent incidences of hypotension, however without evidence of serious compromise of cardiovascular status.

In the neonatal randomized trial, adverse effects identified were lung overdistention, air leak, intra-ventricular hemorrhage (IVH), bradycardia, mucus plugging of the endotracheal tube, and hypotension. There were no statistical differences in any of the adverse effects as compared to those reported in the conventionally treated patients.

High frequency ventilation, as with conventional positive pressure ventilation, has inherent risks in this patient population. These possible adverse effects include: under/over ventilation, under/over humidification, intra-ventricular hemorrhage (IVH) in the neonate, bronchopulmonary dysplasia (BPD), necrotizing tracheal bronchitis (NTB), atelectasis, hypotension, pneumothorax, pneumopericardium, pneumomediastinum, pneumoperitoneum, and pulmonary interstitial emphysema (PIE). The reported frequency of these occurrences are similar to conventional ventilation.

Terms

WARNINGS	identify conditions or practices that could result in serious adverse reactions or potential safety hazards.
CAUTIONS	identify conditions or practices that could result in damage to the ventilator or other equipment.
NOTES	identify supplemental information to help you better understand how the ventilator works.

Warnings

The following warnings must be read and understood before an attempt is made to operate the Model 3100A HFOV:

- Servicing of this instrument is restricted to factory-trained personnel only.
- Sudden unexplained bradycardic events associated with no other clinical changes are possible in neonates who are being weaned or close to being weaned from HFOV therapy. These events may signal possible rapid improvements in patient lung compliance with overdistention during HFOV therapy and may require rapid weaning of $\overline{Paw}$ or switching to conventional ventilation.

- Do not attempt to defeat the proper connection of the ground wire as it may cause damage to the device or interconnected equipment and could be injurious to the patient or to those associated with the device use. This device is factory equipped with a hospital-grade AC power plug. Grounding reliability can only be assured when connected to a tested receptacle labeled "Hospital Grade."
- Do not operate radio transmitters within 20 feet of this instrument. This may result in erroneous pressure readings leading to false alarms and automatic shutdown.
- Do not shorten the 30" bias flow tube provided with the patient circuit as this may reduce the maximum ΔP by allowing the oscillatory pressures to be attenuated by closer proximity to the volume of the humidifier canister.
- Do not attempt to substitute another circuit configuration as this could result in injury to the patient and/or the operator or equipment damage. The Patient Circuit described in this manual is specifically designed for patient use with the Model 3100A HFOV.
- The operational verification and startup procedure must be followed before beginning ventilation of a patient. If at any time during the operational verification and startup procedure any abnormal function of the Model 3100A HFOV is noted, do not proceed with patient ventilation as this could cause patient injury or death. Contact SensorMedics Technical Support before proceeding any further.
- An audible alarm indicates the existence of a condition which could be harmful to the patient and should *never* go unattended. Failure to respond to alarms could result in injury (including death) to the patient and/or damage to the ventilator.
- Due to the possibility of explosion, the ventilator should not be used in the presence of flammable anesthetics.
- Under no circumstances should the proximal airway gas temperature exceed 41°C. This could result in injury to the patient's upper airway membranes.
- Failure to comply with the recommended maintenance procedures described in this manual could result in injury to the patient or operator, or damage to the equipment.

Cautions

The following Cautions must be read and understood before an attempt is made to operate the Model 3100A HFOV:

- Follow closely the recommendations contained in Chapter 5, Clinical Guidelines, regarding the use of chest radiographs and cerebral ultrasound to monitor patient condition. During HFOV, as with all ventilators, the relationship between improvement in lung compliance, inadvertent increases in lung volume, increased pleural pressure, and decreased venous return is a matter of concern, since it may result in decreased cardiac output and a possible increase in the risk of IVH.
- Patient weight is an important guideline as to lung volume and anatomical dead space, as well as the metabolic demand placed on ventilation. While the maximum displacement volume of the 3100/3100A is approximately 365 ml, the actual volume delivered to the patient is dependent on the power setting, frequency, endotracheal tube size, and patient respiratory system compliance. Therefore, you should pay special attention to ventilatory requirements and $PaCO_2$ in larger children. Please review Chapter 5 of this manual, "Clinical Guidelines."
- The patient's $tcPCO_2$ and $tcPO_2$ or SpO_2 must be monitored continuously to insure that blood gases are at the proper level. It is important that an unrestricted and unobstructed

patient airway be maintained during HFOV. To ensure a clear patent airway, always maintain proper suctioning procedures as described in the Suctioning Guidelines section of Chapter 5, Clinical Guidelines. Since only proximal airway pressure is measured, no alarm will occur in the event of an obstruction or restriction.

- Ensure that the water-trap stopcock is closed prior to performing a Patient Circuit Calibration. If the stopcock is left open, Patient Circuit Calibration (39-43 cmH2O) may not be achievable, and the deliverable $\overline{P_{aw}}$ will be reduced.
- Deviation from the assembly methods described in this manual, could damage the Model 3100A, render it mechanically unstable, or cause it to malfunction. If any questions arise regarding assembly, please contact SensorMedics Technical Support before proceeding.
- Care should be taken not to crimp or perforate any of the control or sensing lines (running to or from the Patient Circuit) during the assembly, operating or cleaning of the ventilator as this will cause malfunction of the Safety Alarms, Warning Alarms, Caution Alarms, and/or Pressure Limit Controls.
- When connecting the Patient Circuit, make certain that it is properly supported and oriented by the support arm. Failure to do so could result in inadvertent Patient Circuit disconnection due to oscillatory forces or could result in collection of humidifier condensate in the patient airway.
- If the temperature probe is wiped with alcohol, allow the alcohol to evaporate completely before inserting it into the circuit. Residual alcohol can weaken the acrylic adapter and cause fracturing.
- Proper operation of the ventilator must be verified prior to each use. Refer to Chapter 4, Operational Verification and Startup Procedures. The alarm functions tested in this procedure verify the capability of the device to detect and indicate conditions which could have a harmful effect on the patient.
- Touch the outer metal cabinet of the instrument before touching any other component to avoid possible instrument component damage from Electrostatic Discharge.
- When the ventilator is connected to a patient, someone must be in attendance at all times to react to alarms or other indications of a problem.
- The Inlet Filter Cartridges for the blended gas and the air inputs to the ventilator must be changed at least every 500 hours of operation as described in Chapter 6, Maintenance and Troubleshooting. Failure to replace a Filter Cartridge or substitution of an incorrect cartridge could result in injury to the patient and/or damage to the equipment. Use only SensorMedics Inlet Filter Cartridges.
- The filter cartridge body must be screwed back on securely. Cross-threaded or loose installation will result in leaks and possible dislodging of the cartridge body. The ventilator WILL NOT FUNCTION if the cartridge body is dislodged.
- The cover enclosing the control package, column, or any other portion of the ventilator must not be removed by the user. To avoid electrical shock hazard, please refer all service requiring cover removal to a factory trained, biomedical equipment service technician.
- Recheck and readjust limit level after any ΔP change has been made. If the oscillatory amplitude (ΔP) is changed after the limit level has been set, the actual limit level will change slightly, in the same direction as the ΔP was changed.

- Troubleshooting the 3100A should be done *"OFF PATIENT"* to avoid any potentially dangerous situations such as abrupt changes in the $\bar{P}aw$.
- Do not use extraneous ventilator circuit attachments (such as a suction port) without a secondary external alarm capable of detecting ventilator disconnection. Due to their inline pressure characteristics, such attachments could possibly keep the $\bar{P}aw$ alarm from detecting an accidental ventilator circuit disconnection.
- Fractional concentration of inspired oxygen should be verified with an oxygen monitor. Administration of excessive oxygen to a patient may be harmful. It is imperative that the prescribed gas mixture is delivered by the blending system.
- The Water Trap must be drained at intervals as described in Chapter 6, Maintenance and Troubleshooting. If the ventilator is operating, leave a small amount of water at the bottom of the Water Trap container to act as a flow and pressure seal between the ventilator and the output of the drain.
- To help prevent patient injury due to humidifier malfunction, use of a humidifier with the following characteristics is strongly recommended:

  (a) Thermally protected heater.

  (b) Alarms on overfilled water reservoir.

  (c) Alarms on under-filled water reservoir.

  (d) Alarms when electrically open or shorted temperature probe detected.

  (e) Alarms at probe temperatures > 41°C.

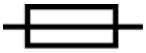
  (f) Alarms when dislodged temperature probe detected.
- Do not place fluid-containing accessories, accessories that weigh more than ten pounds, or accessories that extend more than six inches above the ventilator electronics package or beyond its sides, on the Control Package of the ventilator. Doing this could cause damage to the ventilator, or could cause the ventilator to tip over, resulting in patient or user injuries and/or damage to the equipment.
- Do not over turn or force the Patient Circuit Calibration adjustment screw as this may cause damage to the device. When it is nearing its adjustment limit, it will reach a mechanical stop.
- Do not allow liquids to penetrate the casing of the ventilator as this may result in machine failure or malfunction.
- Do not use a liquid sterilization agent on the outside of the ventilator as this may cause damage.

CAUTION: Federal law restricts this device to sale by, or on the order of a physician.

CAUTION: Not suitable for use in the presence of flammable anesthetics.

Service of this instrumentation is restricted to Factory Trained Personnel only.

Symbols

Symbol	Compliance	Meaning
	Symbol #03-02 IEC 60878	Indicates ATTENTION, consult ACCOMPANYING DOCUMENTS
	Symbol #5016 IEC 60417	This symbol indicates a FUSE.
	Symbol #5019 IEC 60417 Symbol #01-20 IEC 60878	This symbol indicates protective EARTH (ground).
	Symbol # 5333 IEC 60417 Symbol #02-03 IEC 60878	This symbol indicates TYPE B equipment, which indicates equipment that provides a particular degree of protection against electric shock, particularly with regards to allowable leakage current and reliability of the protective earth connection.
	Symbol #5032 IEC 60417 Symbol #01-14 IEC 30878	This symbol indicates the equipment is suitable for alternating current.
	Symbol #5007 IEC 60417 Symbol #01-01 IEC 60878	Indicates ON (Power)
	Symbol #5008 IEC 60417 Symbol #01-02 IEC 60878	Indicates OFF (Power)
	SensorMedics Symbol	Position Lock. Clockwise rotation locks instrument top. Counter-clockwise rotation unlocks instrument top, allowing it to be swiveled for best view of front controls and displays.

Chapter 1 Introduction, Systems & Safety Features

System Diagrams

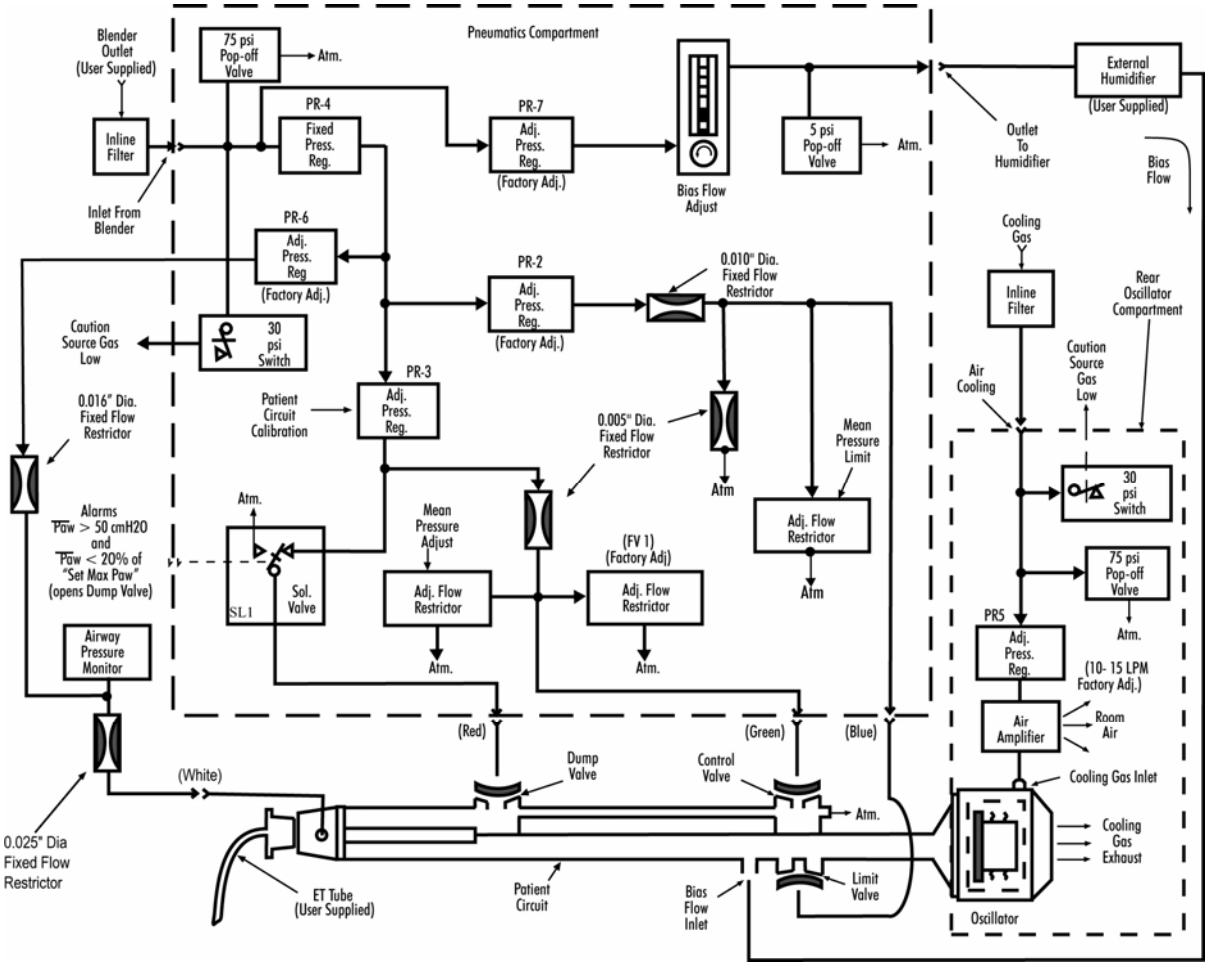


Figure 1.1. Pneumatic System Block Diagram for Part Number 770860.

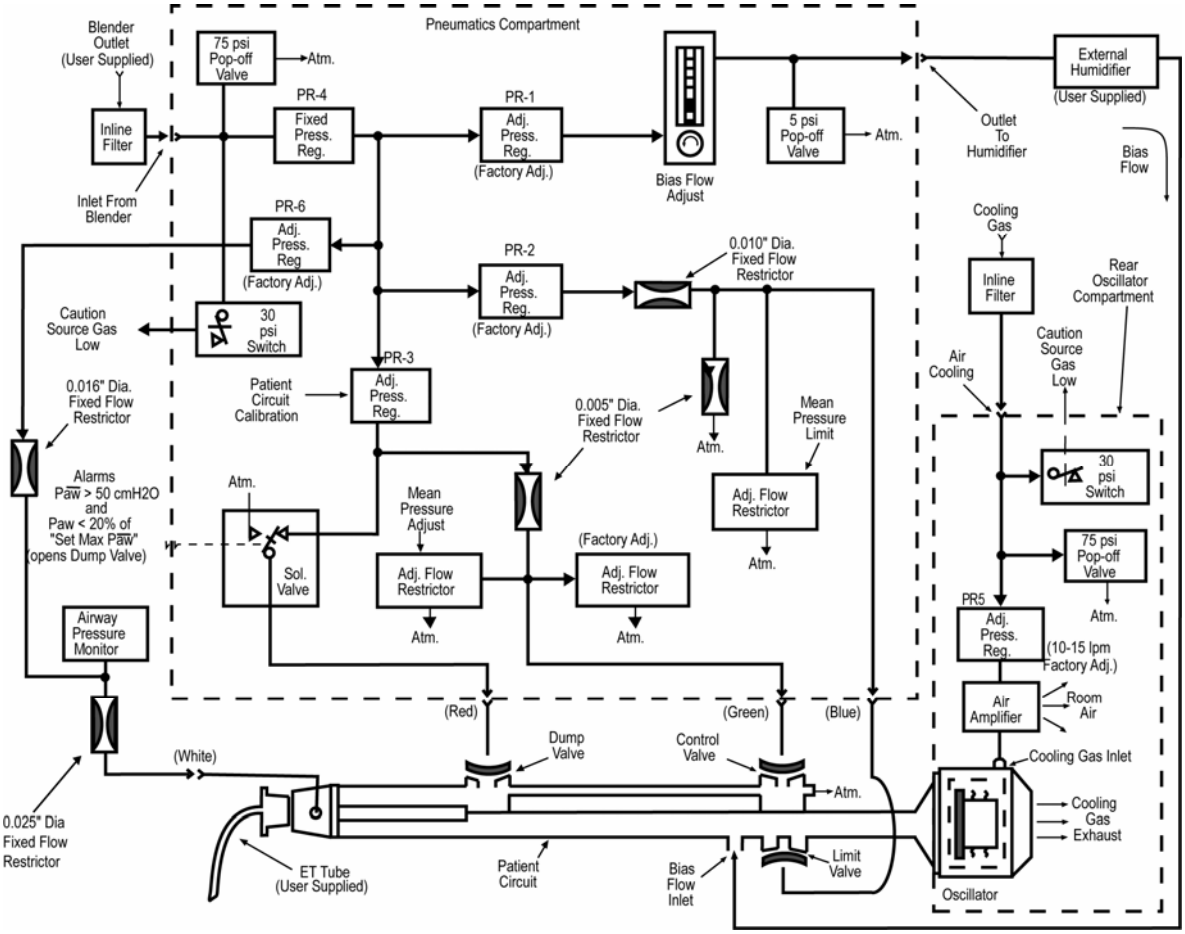


Figure 1.2 Pneumatic System Block Diagram for Part Number 766526

Introduction to the 3100A System

The 3100A HFOV system consists of eight linked subsystems. Six of these are included as part of the Model 3100A delivered to the customer, but two of them must be provided by the user.

The two subsystems to be provided by the user are:

- An External Air/O_2 Blender
- An External Humidifier

The subsystems included with the ventilator are:

- The pneumatic logic and control system.
- The patient circuit.
- The oscillator subsystem.
- The airway pressure monitoring system.
- Electronic controls and alarms.
- Electrical power supply.

External Air/Oxygen Blender

Both oxygen and air sources are required for the 3100A. These sources feed a user-provided Air/Oxygen Blender. The air source also provides cooling to the Oscillator by means of a special pneumatic control system. The flow requirements for both the blender and for the air cooling of the Oscillator are described in Appendix B Specifications.

CAUTION

Fractional concentration of inspired oxygen should be verified with an oxygen monitor. Administration of excessive oxygen to a patient may be harmful. It is imperative that the prescribed gas mixture is delivered by the blending system.

External Humidifier

Although it functions with the patient circuit, the external humidifier is treated as a separate subsystem because it is provided by the user. The humidifier that is used *must* be a heated humidifier specifically manufactured for neonatal/pediatric use. It must be capable of a flow range up to 40 LPM. The temperature control can be either closed or open loop; however, proximal airway gas temperature must be monitored. Two ports for the temperature probe are provided on the Patient Circuit. These will be discussed later.

WARNING

Under no circumstances should a proximal airway gas temperature of 41°C be exceeded. This could result in injury to the patient's upper airway membranes.

CAUTION

To help prevent patient injury due to humidifier malfunction, we strongly recommend using a humidifier with the following characteristics:

a. Thermally protected heater.
b. Alarms on overfilled water reservoir.
c. Alarms on under filled water reservoir.
d. Alarms when open or shorted temperature probe is detected.
e. Alarms at probe temperatures > 41°C.
f. Alarms when dislodged temperature probe is detected.

Connecting the humidifier is described in more detail in Chapter 2, Assembly and Installation. Two standard adapters are provided for connecting the 3/8" I.D. tubing to and from the humidifier.

The Pneumatic Logic and Control System

The Blender feeds pressurized blended gas to the Model 3100A Pneumatic Logic and Control Subsystem through an oxygen DISS fitting. Four pneumatic controls are part of this subsystem:

- Bias Flow Control
- Mean Pressure Adjustment
- Mean Pressure Limit Control
- Patient Circuit Calibration Adjustment

Bias Flow Control

This control sets the flow of the blended gas that continuously moves past the patient airway.

Mean Pressure Adjustment

This control adjusts the mean airway pressure level on which the oscillatory waveform is superimposed. This mean airway pressure setting along with the oscillatory waveform characteristics determines the resultant $\overline{P_{aw}}$. This control determines the level of Patient Circuit expiratory limb Control Valve restriction in the manner described in the Patient Circuit section below.

Mean Pressure Limit

This control determines the limiting proximal $\overline{P_{aw}}$ within the Patient Circuit Subsystem. This control communicates with the Pressure Limit Valve of the Patient Circuit through a pneumatic control line in the manner described in the Patient Circuit section below.

Patient Circuit Calibration Adjustment

This control is a screwdriver adjustment used to set the maximum mean pressure that can be attained with a particular Patient Circuit under specified conditions (see Chapter 6, Maintenance and Troubleshooting.) This control is used only when the Patient Circuit is replaced or the $\overline{P_{aw}}$ control valve diaphragm of the existing Patient Circuit is changed. The control is necessary because the individual elastic and dimensional characteristics of the $\overline{P_{aw}}$ control valve diaphragm interact with the valve control line pressure to determine the control dial maximum setting.

CAUTION

Do not overturn the Patient Circuit Calibration as this may cause damage to the device. When it is nearing its adjustment limit, it will reach a mechanical stop.

The range, resolution, and accuracy of the pneumatic controls and the characteristics of the various pneumatic connections are described in Appendix B Specifications. Chapter 3 Controls, Displays and Connections provides a detailed description of the functions and use of each control.

WARNING

Do not attempt to substitute another circuit configuration as this could result in injury to the patient and/or the operator, or cause equipment malfunction. The Patient Circuit described in this manual is specifically designed for patient use with the Model 3100A HFOV.

The Patient Circuit

The Patient Circuit combines the three elements necessary for ventilation of the patient using HFOV techniques:

- bias flow/pressure,
- pressure oscillations, and
- pressure limiting.

The Patient Circuit is illustrated here in Figure 1.3 and shown schematically in Figure 1.1.

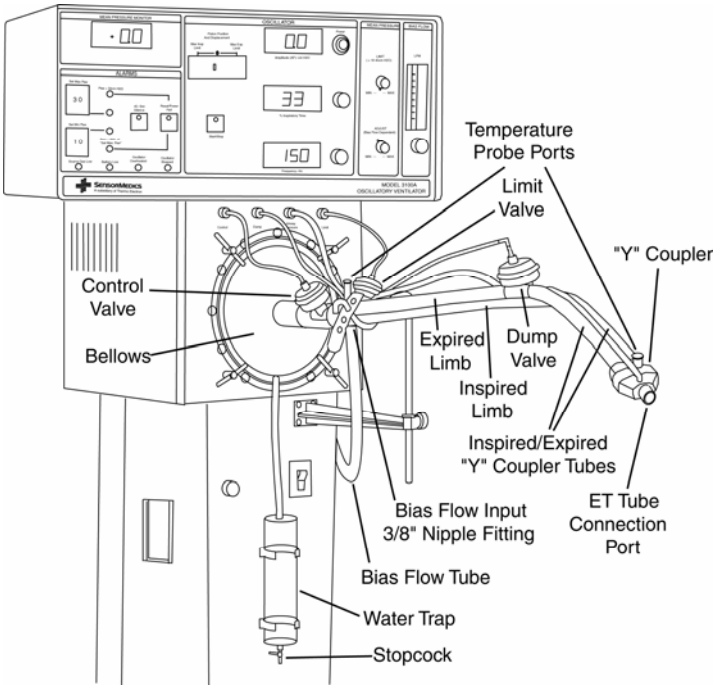


Figure 1.3. Details of Patient Circuit.

During normal operation, humidified, blended bias gas flows into the bias flow tube from the external humidifier. This gas flows into and through the inspiratory limb of the Patient Circuit, through the "Y" coupler and then into the expiratory limb of the Patient Circuit. While passing through the "Y" coupler, the fresh gas exchanges oxygen and carbon dioxide at the ET tube/patient connection.

A proximal airway pressure sensing line made of 1/8" PVC tubing runs from the "Y" coupler to the Airway Pressure Monitor via a white Luer bulkhead fitting near the Patient Circuit connection. The pressure signal is processed to determine various pressure measurements and alarm conditions. The Airway Pressure Monitor and tubing are discussed in a following section.

The expiratory limb carries the exchanged gas to the $\bar{P}aw$ Control Valve. This valve allows two expiratory flow paths. One path is a variable restriction controlled by the $\bar{P}aw$ Control Valve control line extending from the Pneumatic Logic and Control Subsystem via a green Luer bulkhead fitting near the Patient Circuit connection. The other flow path is a fixed orifice that requires a minimum bias flow be maintained through the Patient Circuit to ensure a flow of fresh Bias Gas regardless of the setting of the $\bar{P}aw$ Control Valve.

When the $\bar{P}aw$ Control Valve is adjusted, it adjusts the mean airway pressure at the ET tube/patient connection after about five system time constants have elapsed, but only if the set bias flow and oscillator characteristics remain unchanged for the same time period. Five time constants can vary from about one second to as long as 30 seconds. This time constant varies directly with $\bar{P}aw$ and inversely with bias flow.

The individual elastic and dimensional characteristics of the $\bar{P}aw$ Control Valve diaphragm interact with the valve control line pressure to determine the control dial maximum setting. The Patient Circuit Calibration adjustment control sets the maximum mean pressure that can be attained with a particular Patient Circuit under specified conditions. This control is used only when the Patient Circuit is replaced or the $\bar{P}aw$ control valve diaphragm of the existing Patient Circuit is changed. Refer to Chapter 6, Maintenance and Troubleshooting, for the complete setup procedure.

The Pressure Limit Valve limits the $\bar{P}aw$. When an abnormal condition exists or when the system mean pressure increases due to an inadvertent or deliberate control setting change, this valve acts to limit the mean proximal airway pressure.

Both the $\bar{P}aw$ Control Valve and the Pressure Limit Valve are mushroom valves that must be replaced periodically. See Chapter 6, Maintenance and Troubleshooting for replacement instructions.

The Dump Valve is activated by Electronic and Pneumatic Controls only when the following safety alarms are activated:

1. $\bar{P}aw$ > 50 cmH_2O
2. $\bar{P}aw$ < 20% of "Set Max $\bar{P}aw$"

The Dump Valve, when activated, opens the Patient Circuit to ambient air. When the safety alarms have been activated, this allows the patient to breathe spontaneously at normal atmospheric pressure. In an emergency situation, the Dump Valve helps to prevent a decrease in cardiac output due to sustained elevated Patient Circuit pressure or atelectasis due to a negative Patient Circuit pressure.

The Dump Valve is a mushroom valve that must be replaced at regular intervals as described in Chapter 6.

Two ports are provided for inserting the temperature probe of the External Humidifier. One is near the patient "Y"; the other is near the Pressure Limit Valve.

The inspiratory limb acts as the propagation means for the pressure oscillations generated by the Oscillator. A typical airway pressure oscillatory waveform is illustrated in Figure 1.4.

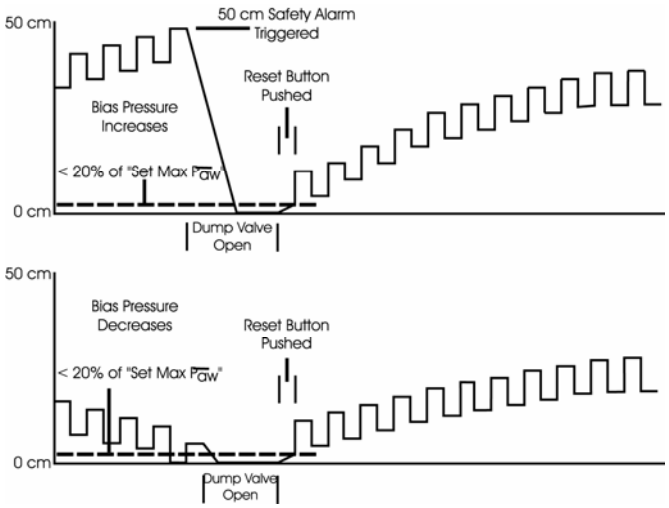


Figure 1.4. Typical oscillatory proximal airway pressure waveforms with dump valve activation.

This figure also illustrates the activation of the dump valve due to the $\bar{P}aw$ being greater than the 50cmH_2O limit or less than the 20% Set Max $\bar{P}aw$ limit.

> **CAUTION**
>
> The Water Trap must be drained at intervals as described in Chapter 6, Maintenance and Troubleshooting.

The function of the controls shown here and the function of the safety alarms are discussed further in Chapter 3, Controls, Indicators, and Connections. Assembly of the Patient Circuit onto its mounting arm and its connection to the rest of the HFOV system is discussed in Chapter 2, Assembly and Installation.

The Oscillator

The components of the Oscillator are illustrated in Figure 1.5. The design incorporates an electronic control circuit (square-wave driver) which drives a linear motor which in turn drives a piston assembly. It is very similar to a permanent magnet speaker.

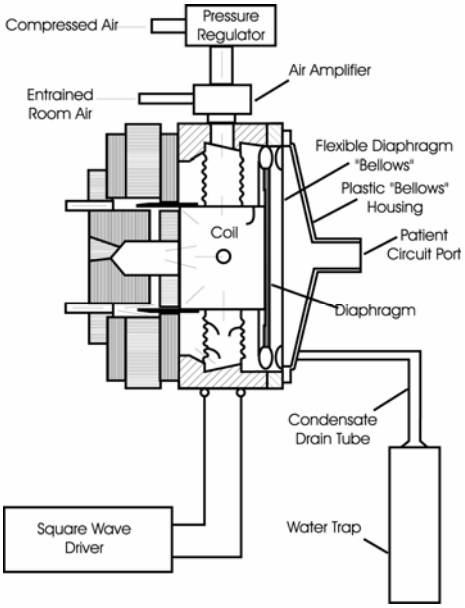


Figure 1.5. Details of Oscillator.

One of the major features of the design is that there is no physical contact between the permanent magnet and the electrical coil which is suspended by “spiders” within the permanent magnet. This results in a very efficient frictionless oscillator system with an operational life of more than 4,000 hours.

When the square-wave driver is of positive polarity, it drives the electrical coil and the attached piston forward in the direction of the patient (inspiration). When the polarity is negative, it drives the electrical coil and the attached piston in the opposite direction (expiration).

The distance the piston is driven in each direction is determined by the following factors:

- magnitude of the alternating polarity voltage applied to the electrical coil,
- the Patient Circuit pressure encountered by the piston plate,
- the piston coil counterforce current developed by the Piston Centering Control,
- and the frequency of the square wave.

The voltage of the square-wave driver output is controlled by the Power Control of the Electronic Control and Alarm Subsystem.

There are two mechanical stops which determine the maximum piston displacement in the full inspiration and full expiration directions. The maximum stroke of the piston defined by these stops is approximately 365 milliliters. An infrared sensor is used to track the displacement of the piston head between the mechanical stops for display on a bar graph on the front panel of the Electronics Control and Alarms Subsystem. A control on this subsystem also determines the frequency of the oscillations.

The % inspiratory time is determined by another control on the Electronic Control and Alarms Subsystem. This control sets the relative duration of the successive positive and negative polarity voltages from the square-wave driver which is driving the electrical coil and piston.

As mentioned previously, the displacement of the electrical coil and piston is determined by the magnitude of the voltage applied to the electrical coil. The total transit time required for this displacement is only a matter of milliseconds. Therefore, at the lower oscillation frequencies, the piston will remain stationery at its full-travel position for the majority of that particular respiration phase (inspiratory or expiratory).

As the oscillation frequency increases, the transit time of the electrical coil and piston to its set full displacement will become a larger percentage of the total respiratory phase duration. Although exactly determined by conditions within the Patient Circuit, as frequency is increased the electrical coil and piston are unable to complete full displacement before the square-wave driver switches polarity requiring the travel direction to reverse. Thus, the displacement amplitude of the oscillator piston will decrease as the oscillation frequency is increased.

Refer to Appendix B, Specifications, for details on the range, resolution, and accuracy of the various control functions affecting the Oscillator. Refer to Chapter 3, Controls, Indicators, and Connections, for a full description of the use of these controls.

Because the major portion of the Oscillator is a linear motor, some type of cooling mechanism must be provided for the electrical coil. The cooling source used in the Model 3100A is air flow obtained from a standard 50 psig gas wall outlet. A regulator within the Oscillator Subsystem meters the airflow to a Venturi-type air amplifier at 15 LPM, which then entrains room air at 45 LPM, thus providing 60 LPM of cooling air around the electrical coil.

A thermal cutout circuit has been incorporated into the oscillator to shut it down in case of overheating caused by a cooling system failure. Such a failure, if allowed to occur without oscillator shutdown, could result in the destruction of the oscillator coil's support spiders. The thermal cutout system utilizes a

thermistor on the oscillator coil form to detect temperature rise. Thermal shutdown will occur if coil temperature exceeds 190°C.

Prior to an oscillator thermal shutdown, the operator is given an indication that the coil is overheating. A yellow caution LED on the front panel of the Control Package lights when the coil temperature reaches approximately 175°C.

The Airway Pressure Monitor

The Airway Pressure Monitor is a key subsystem within the Model 3100A HFOV. The majority of the safety and warning alarms rely upon the mean airway pressure determinations of the Airway Pressure Monitor.

The Airway Pressure Monitor senses the pressure within the Patient Circuit through 1/8" tubing running from the "Y" coupler of the Patient Circuit to the airway pressure monitor transducer. A 500 ml/min trickle flow of dry gas from the blender flows constantly from the 3100A to the patient "Y" to keep water vapor from even partially obstructing this pressure sensing pathway.

> WARNING
> Failure to comply with the recommended maintenance procedures for the Airway Pressure Monitor as described in Chapter 6 could result in injury to the patient or operator or could result in damage to the equipment.

The Airway Pressure Monitor processes the instantaneous airway pressure measurements of its pressure transducer to derive the following:

1. Mean airway pressure ($\overline{P_{aw}}$)
2. Oscillatory peak, minus oscillatory trough pressure (ΔP)

Mean Airway Pressure is essentially an arithmetic mean of the airway pressure measurement. It is obtained by filtering the instantaneous pressure signal with a DC to 0.5 Hz. low pass filter.

The ΔP reading is obtained by subtracting the oscillatory trough pressure from the peak pressure.

Specifications for the Airway Pressure Monitor are contained in Appendix B. A detailed description of the use of its control and display is contained in Chapter 3.

Electronic Controls & Alarms

This subsystem contains the oscillator controls and the alarm functions. It consists of various electronic circuits and logic elements. It integrates information received from the Airway Pressure Monitor and causes the ventilator to react in a fashion safest for the patient. It utilizes this information to orchestrate the activity of the Oscillator Subsystem and the Pneumatic Logic and Control Subsystem.

The following are the Oscillator controls which form a part of the Electronic Control and Alarm Subsystem:

1. Power
2. % Inspiratory Time
3. Frequency–Hz
4. Start/Stop

The operation and use of these controls is described in detail in Chapter 3.

The subsystem also contains the following indicators for reporting on the Oscillator Subsystem status:

1. Piston Position and Displacement bar graph
2. Start/Stop LED
3. ΔP digital meter
4. % Inspiratory Time digital meter
5. Frequency digital meter

The coordination of these indicators with the Oscillator Subsystem controls is described in detail in Chapter 3.

The following alarm controls and indicators are part of this section:

1. Max $\overline{P_{aw}}$ exceeded thumbwheel and LED
2. Min $\overline{P_{aw}}$ exceeded thumbwheel and LED
3. $\overline{P_{aw}}$ > 50 cmH_2O LED
4. $\overline{P_{aw}}$ < 20% of "Set Max $\overline{P_{aw}}$"
5. 45-Sec Silence pushbutton and LED
6. Reset pushbutton
7. Battery Low LED
8. Source Gas Low LED
9. Oscillator Overheated LED
10. Oscillator Stopped LED
11. Power Failure LED

The range, resolution, and accuracy of these alarm functions are described in Appendix B. A detailed description of the use of these alarms, controls, and indicators is found in Chapter 3.

The function of the alarms is influenced by inputs from the Airway Pressure Monitor, Oscillator Subsystem, and Pneumatic Logic and Control Subsystem.

The Electrical Power Supply

The Electrical Power Supply converts the AC line voltage to the DC voltages required to power the Electronic Control and Alarms Subsystem, the Airway Pressure Monitor, and the Oscillator Subsystem.

Detailed specifications are listed in Appendix B. Maintenance procedures are covered in Chapter 6.

Safety Features

The Model 3100A HFOV system has been designed with numerous safety features both to help avoid patient injury and to protect the equipment from damage. These are the safety features are incorporated into the design of the various subsystems:

1. Warning Alarms
2. Safety Alarms
3. Power Failure Alarm

4. Oscillator Stopped Alarm
5. Caution Alarms
6. Oscillator thermal cutout
7. Water trap for condensate
8. Pressure relief valves to protect the equipment from over-pressure damage
9. Oscillator startup logic to prevent application of excessively high or low oscillatory pressures to patient

Warning Alarms

There are two warning alarms. These are the Max $\overline{Paw}$ and Min $\overline{Paw}$ Exceeded settings and indicators. These alarms automatically reset after correction of the alarm condition. They are indicated by red LED's and a 3khzmodulated tone. No machine action is taken, but user intervention is required.

Safety Alarms

The Safety Alarms consist of the $\overline{Paw}$ > 50 cmH_20 and the $\overline{Paw}$ < 20% of "Set Max $\overline{Paw}$" alarms. They are indicated in the same manner as the Warning Alarms described above. If either of these $\overline{Paw}$ alarms is activated, the oscillator stops (bias flow continues) and the Dump Valve opens the Patient Circuit to atmospheric pressure. The $\overline{Paw}$ >50cmH_2O alarm can only be reset by pressing the Reset Button once the high pressure condition has been corrected. The $\overline{Paw}$ < 20% of "Set Max $\overline{Paw}$" alarm will reset immediately after correction of the low pressure condition. The $\overline{Paw}$ >50cmH_2O alarm is preset, but the $\overline{Paw}$ < 20% of "Set Max $\overline{Paw}$" alarm setting will always be at 20% of the level of the Max $\overline{Paw}$ Exceeded Warning Alarm thumbwheel setting.

Power Fail Alarm

When the Power Failure Alarm is activated, no other machine actions are taken other than the energizing of a red LED and a 3khz modulated tone. The Power Failure Alarm is reset by pushing the Reset button whether or not the alarm condition (removal of or inadequate power supply to the Electronic Control and Alarms Subsystem) has been corrected. To restart the oscillator it will then be necessary to press the Start/Stop Switch. It is normal for the Battery Low LED to light when the reset button is pressed.

Caution Alarms

The Caution Alarms activate a yellow LED only; no audible alarm occurs. The Caution Alarms are the following: Battery Low, Source Gas Low, Oscillator Overheated and 45-Sec Silence. The Battery Low, Source Gas Low and the Oscillator Overheated Caution Alarms are reset only by correction of the caution condition by the user. The 45-Sec Silence caution indicator will be illuminated for the duration of the 45-second alarm silence duration. During this 45-second period, the audible alarm will be silenced regardless of the alarm condition. All visual alarm indicators will operate normally.

Oscillator Stopped Alarm

The Oscillator Stopped Alarm will occur if ΔP is < 5 to 7 cmH_2O. A red LED and audible 3K-Hz. indication occurs. No action is taken by the machine and the alarm resets automatically upon correction of the alarm condition. Note that the oscillator may in fact be operating, but the resultant ΔP is below 5

to 7 cmH_20. If the oscillator is disabled by pushing the Start/Stop button, the Oscillator Stopped alarm is disabled.

WARNING

An audible alarm indicates the existence of a condition potentially harmful to the patient and should not go unattended. Failure to respond to alarms could result in injury (including death) to the patient and/or damage to the ventilator.

CAUTION

When the ventilator is connected to a patient, it is imperative that someone be in attendance at all times in order to react to any alarms and to detect other indications of a problem.

Thermal Cutout Safety System

A thermal cutout safety feature has been incorporated into the Oscillator Subsystem. This feature shuts down the oscillator if overheating occurs. If the oscillator were not shut down, such overheating could result in the destruction of the oscillator coil's support spiders. The thermal cutout system utilizes a thermistor on the oscillator coil form to detect temperature rise. Thermal shutdown will occur if coil temperature exceeds 190°C.

Prior to an oscillator thermal shutdown, the operator is given an indication that the coil is overheating. A yellow caution LED on the front panel of the Control Package lights when the coil temperature reaches approximately 175°C.

Water Trap

A Water Trap is incorporated into the Oscillator subsystem to help eliminate condensate from the Patient Circuit. The Water Trap is easily emptied as described in Chapter 6, Maintenance and Troubleshooting.

CAUTION

The Water Trap must be drained at intervals as described in Chapter 6, Maintenance and Troubleshooting. If the ventilator is operating, leave a small amount of water at the bottom of the Water Trap container to act as a flow and pressure seal between the ventilator and the output of the drain.

Pressure Relief Valves

There are mechanical pressure relief devices to protect the equipment from damage. A 75 psig mechanical relief valve protects the “Inlet from Blender” and the “Air Cooling Inlet” connections. The “Outlet to Humidifier” connection is protected by a 5 psig mechanical relief valve. These devices function whether the Model 3100A HFOV is electrically energized or not.

Oscillator Startup

The oscillator will not start unless the controls are used in the proper sequence and/or set to the proper range. The startup procedure is described in Chapter 4, Operational Verification and Startup Procedures.

Chapter 2 Assembly and Installation

This chapter covers the unpacking, assembly, and installation of your 3100A HFOV system.

Unpacking

The Model 3100A HFOV is shipped in one crate, containing the instrument (preassembled control package, column, and pedestal) and several smaller cartons containing:

- Patient Circuit support arm and cradle.
- Four complete patient circuits, broken down into three segments and packaged four to a box.
- Humidifier input and output hoses/adapters.
- A box of ten spare Inlet Filter cartridges for blended gas and air inputs.
- Operator's Manual.
- Humidifier mounting bracket adapters.

If, when you are unpacking your ventilator, you notice that anything is damaged or missing, please contact VIASYS Healthcare Customer Care Helpline at the numbers given in Appendix A.

Assembly

> CAUTION
>
> Deviation from the assembly methods described here could damage the Model 3100A, or cause it to malfunction. If any questions arise regarding the assembly procedure, please contact SensorMedics Technical Support before proceeding.

The Control Package, the Column and the Pedestal are factory preassembled. Carefully remove them from their shipping container and place on a flat and level surface. Lock the locking wheels.

Patient Circuit Support Arm

Using a flathead screwdriver, assemble the Patient Circuit support arm prior to attaching the Patient Circuit.

Attach the vertically-adjustable rod to the end of the support arm so that it will cradle, in its curved end, the main tube of the Patient Circuit. Tighten the thumbscrew crosspiece to secure it at the height desired.

> *Note*
>
> *The angle of the Patient Circuit can also be controlled by loosening the thumbscrew on the cradle rod and sliding it either up or down. Always be certain to retighten the thumbscrew.*

CAUTION

When connecting the Patient Circuit, make certain that it is properly supported by the support arm. Failure to do so could result in inadvertent Patient Circuit disconnection due to oscillatory forces or could result in collection of humidifier condensate in the patient airway.

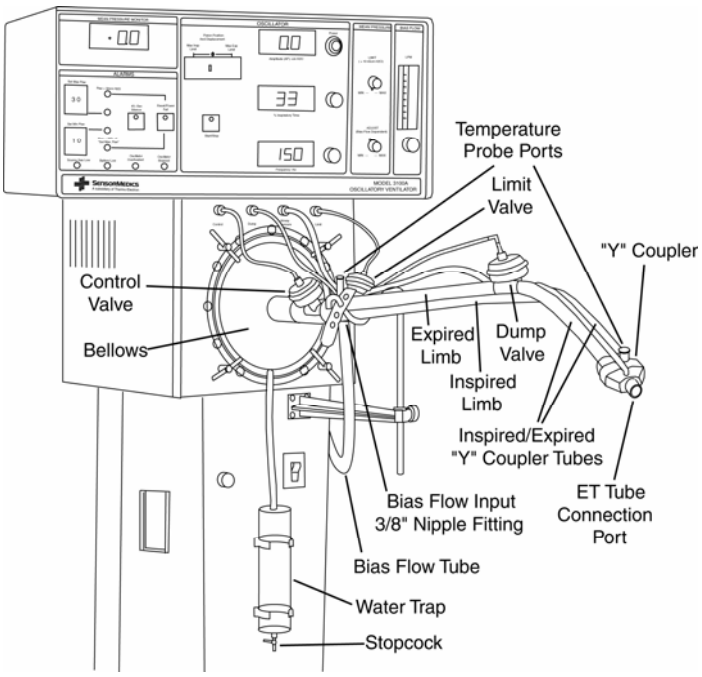


Figure 2.1 Details of Patient Circuit.

Assembling the Patient Circuit

Use figure 2.1 as a guide when assembling the patient circuit.

1. Connect the patient circuit body to the bellows/water trap assembly and snap the three identical cap/diaphragm assemblies onto the three valve bodies located on the patient circuit body.
2. Attach this assembled patient circuit to the face of the oscillator compartment using the four T-handle, quarter-turn fasteners.
3. Attach the three color-coded tubes to their corresponding valve caps, using the following color-coding scheme:

Color of Line	Attaches To
Blue	$\overline{Paw}$ Limit Valve
Green	$\overline{Paw}$ Control Valve
Red	Dump Valve
Clear	$\overline{Paw}$ Sensing Port

The differing lengths and color coding of the tubes and the physical arrangement of the valves within the Patient Circuit minimize the possibility of cross-connection.

CAUTION

Care should be taken not to crimp or perforate any of the control or sensing lines (running to or from the Patient Circuit) during assembly or operation of the ventilator, as this will cause malfunction of the Safety Alarms, Warning Alarms, Caution Alarms, and/or Pressure Limit controls.

4. Attach the 1/8" PVC pressure-sense line (captive to the Patient Circuit "Y") to the bulkhead luer fitting marked "Airway Pressure."
5. Finally, insert the humidifier temperature probe in the tapered-opening near the patient "Y." Note that an identical such port with a removable plug in it is located at the opposite end of the Patient Circuit. This alternate location for the temperature probe is for use with patients who are in an Isolette. Always insert the plug in the unused port.

CAUTION

If you wipe the temperature probe with alcohol, allow the alcohol to evaporate completely before inserting it into the circuit. Residual alcohol can weaken the acrylic adapter and cause fracturing.

Note

Always insert the provided plug into the unused temperature probe port. Failure to do so will allow a leak of sufficient magnitude that the minimum $\overline{P_{aw}}$ necessary to allow the oscillator to start will not be achieved.

Use the cradle rod adjustment already described to maintain the proper Patient Circuit height and angle. The proper angle will allow condensate to run downward into the Water Trap mounted on the Column.

WARNING

Do not attempt to substitute another circuit configuration. This could result in injury to the patient and/or operator, or cause equipment damage. The Patient Circuit described in this manual is specifically designed for patient use with the Model 3100A HFOV.

Incorporation of Blender and Humidifier into System

Obtain an External Air/O_2 Blender and an External Humidifier for incorporation into the system. Attach these devices to the Patient Circuit using the attachment accessories supplied and using Figures 2.1 and 2.2 as a guide. The following connections be made:

Device	Input Connection(s) From	Output Connection To
Air/O_2 Blender	(a) Hospital Air DISS connection (b) Hospital Oxygen DISS connection	Control Package rear panel "INLET FROM BLENDER" DISS fitting
Humidifier	Control Package rear panel "OUTLET TO HUMIDIFIER"	Patient Circuit Bias Flow Connection

3/8" barbed fitting 3/8" nipple fitting

There is an additional connection from the Hospital AIR DISS connection to the Column DISS Air fitting marked “AIR COOLING.”

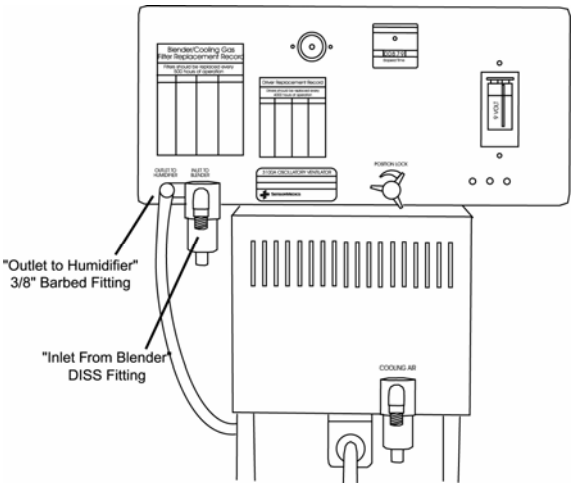


Figure 2.2. Rear Panel Connections.

WARNING

Do not shorten the bias flow tube provided with the patient circuit, as this may reduce the maximum ΔP by allowing the oscillatory pressures to be attenuated by closer proximity to the volume of the humidifier canister.

CAUTION

The inlet filter cartridges for the blended gas and the air inputs to the ventilator must be replaced at least every 500 hours of operation as described in Chapter 6, Maintenance and Troubleshooting. Failure to replace a filter cartridge or substitution of an unauthorized cartridge could result in injury to the patient and/or damage to the equipment. Use only SensorMedics P/N 767163 box of 10.

Find a convenient power outlet for connection to the Model 3100A with a minimum rating compatible with the HFOV power ratings described in Appendix B.

WARNING

Do not attempt to defeat the proper connection of the ground wire. This may cause damage to the device or interconnected equipment and could be injurious to the patient or to those associated with the device use. This device is factory equipped with a hospital-grade AC power plug. Grounding reliability can only be assured when connected to a tested receptacle labeled "Hospital Grade."

CAUTION

Proper operation of the ventilator must be verified prior to each use. Refer to Chapter 4, Operational Verification and Start-up Procedures.

WARNING

Do not operate radio transmitters within 20 feet of this instrument. This may result in erroneous pressure readings leading to false alarms and automatic shut-down.

Pre-Use Cleaning

The 3100A requires no preliminary cleaning before initial use. The Patient Breathing Circuit components, though clean, are not shipped sterile. If desired, the circuit body may be disinfected before using according to the instructions in the "Changing the Patient Circuit" section of Chapter 6, Maintenance and Troubleshooting.

The 3100A High Frequency Oscillatory Ventilator is now ready for Operational Verification and Start-Up (see Chapter 4). We recommend that you familiarize yourself with the location and functioning of the controls (see Chapter 3) prior to starting the ventilator.

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Chapter 3 Controls, Indicators and Connections

This chapter describes the location, function, and use of each control, indicator, and connection on the Model 3100A HFOV. They are illustrated with reference numbers on the illustrations contained within this chapter. Detailed specifications of the resolution and accuracy of controls and indicators are contained in Appendix B. The theory of operation of the 3100A system and each of its subsystems is explained in Chapter 1, Introduction, System and Safety Features.

CAUTION

Proper operation of the ventilator must be verified prior to each use. Refer to Chapter 4, Operational Verification and Startup Procedures. The alarm functions tested in this procedure verify the capability of the device to detect and indicate conditions which could have a harmful effect on the patient.

Front and Side Panel – Control Package

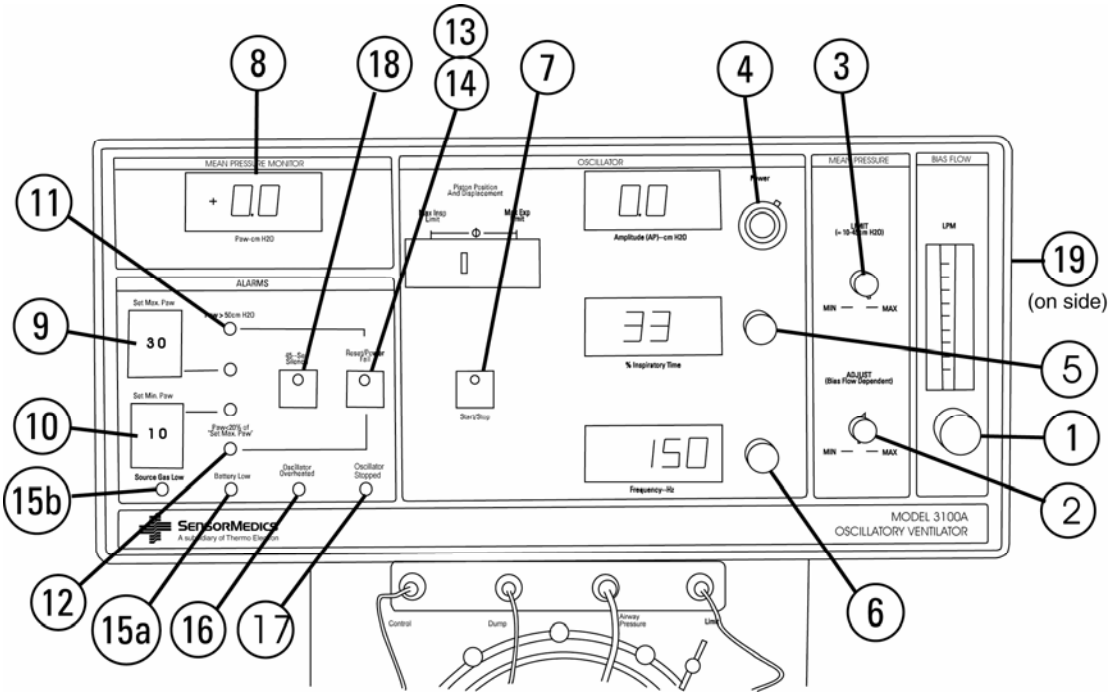

Figure 3.1. Front Panel Controls and Indicators.

The numbers shown on Figure 3.1 correspond to the following numbered descriptions.

1. Bias Flow

Controls and indicates the rate of continuous flow of humidified blended gas through the Patient Circuit. The control knob is a 15-turn pneumatic valve which increases flow as it is turned counterclockwise.

The rate of flow is indicated by a ball float within a rotometer glass tube graduated from 0 to 60 LPM in 5 LPM increments. The flow is read by aligning the center of the ball float with the rotometer scale mark corresponding to the adjusted flow. The maximum achievable rate of flow is internally limited to 40 LPM.

2. Mean Pressure Adjust

Adjusts the mean airway pressure ($\bar{P}aw$) by controlling the resistance of the $\bar{P}aw$ Control Valve. (See Figure 3.2 for Patient Circuit details.) This control is a clockwise increasing 1-turn pneumatic valve.

The adjustment affected by this control is read on the Mean Pressure Monitor (8).

Since this control is not a closed-loop control, $\bar{P}aw$ will change if the bias flow setting is changed. Increasing the bias flow will increase the $\bar{P}aw$. In addition, since the oscillatory pressure waveform introduced by the Oscillator Subsystem is nonsymmetrical, adjustment of the oscillator controls will also vary the $\bar{P}aw$.

When adjusted, this control fixes the mean pressure at the ET tube/patient connection after about five system time constants have elapsed but only if set bias flow and oscillator characteristics remain unchanged for the same time period. Five time constants will vary from about one second to as long as 30 seconds. This time constant varies inversely with both $\bar{P}aw$ Control Valve resistance and bias flow setting.

Changes in the following oscillator controls may necessitate readjustment of the mean pressure to maintain a constant $\bar{P}aw$:

- Frequency,
- % Inspiratory Time,
- Power (and resultant ΔP change), and
- Piston Centering.

Frequency affects the $\bar{P}aw$ adjustment slightly, but at higher frequencies the amplitude of the oscillator piston movement may be attenuated due to slew rate limiting. (The transit time of the piston is greater than the cycle time required by the Frequency adjustment.)

Since the % Inspiratory Time adjustment affects the symmetry of the oscillatory waveform, it will directly cause a change in the $\bar{P}aw$ when readjusted.

A change in the ΔP will cause a change in the percent of the $\bar{P}aw$ contributed by any nonsymmetrical oscillatory waveform. Thus, $\bar{P}aw$ will change and will need to be readjusted if an unchanged $\bar{P}aw$ is desired.

With the oscillator off, the Mean Pressure Adjust control is capable of achieving 41 cmH_2O $\bar{P}aw$ at a Bias Flow of 20 LPM with the patient circuit calibrated to the system. $\bar{P}aw$ will generally increase moderately with the oscillator running.

Refer to Chapter 4, Operational Verification and Startup Procedures, for an explanation of the mean airway pressure setup procedure.

3. Mean Pressure Limit

Controls the limit above which proximal $\bar{P}aw$ cannot be increased by setting the control pressure of the Pressure Limit Valve. This control is a single-turn, clockwise increasing, pneumatic valve. Its range is approximately 10 to 45 cmH_2O.

The $\bar{P}aw$ Limit Control must be set to a level which is higher than the range of normal operating $\bar{P}aw$. The control is used to help protect the patient if an accidental over-pressure situation occurs within the Patient Circuit.

> **CAUTION**
>
> Recheck and readjust limit level after any ΔP change has been made. If the oscillatory amplitude (ΔP) is changed after the Safety Limit level has been set, the actual limit level will change slightly, in the same direction as the ΔP was changed.

4. Power/ΔP

Determines the amount of power that is driving the oscillator piston to and fro. The Power control is a 10-turn, electrical potentiometer covering the power range of 0 to 100 %. The knob scale is a 10-turn locking dial that is not calibrated in % power but marked for purposes of establishing reference points.

The effect of this control is to change the displacement of the oscillator piston and hence the oscillatory pressure ΔP.

The Power setting interacts with the $\overline{P_{aw}}$ conditions existing within the Patient Circuit to produce the resultant ΔP. The ΔP is numerically displayed on the digital meter adjacent to the Power control and the causative piston motion is graphically displayed on the 17-segment bar graph labeled "Piston Position and Displacement."

The graphical display allows the user to determine if the oscillator piston has been properly centered or if it is striking the mechanical stop for either full inspiration or full expiration. These limits are labeled on the bar graph "Max Insp Limit" and "Max Exp Limit" respectively.

Allowing the piston to strike either mechanical stop for an extended period of time could reduce the life of the oscillator mechanism and should be avoided. The condition can occur if the Power control is adjusted too high for the $\overline{P_{aw}}$ conditions desired or the Power control is unchanged and the $\overline{P_{aw}}$ is reduced. Refer to Piston Centering Control (30) in this chapter.

Refer to Chapter 4, Operational Verification and Startup Procedures, for a description of the adjustment technique for setting the Power control.

5. % Inspiratory Time

Determines the percent of the oscillator cycle time that the piston is traveling toward or is at its final inspiratory position. The control is a 10-turn electrical potentiometer and covers the range of 30 to 50%. The setting is numerically displayed on the digital meter adjacent to the control.

Changing the % Inspiratory Time control could have an effect on the position of the oscillator piston. At higher frequencies, changing the % Inspiratory Time from at or near 50% toward 30% may decrease the displacement. This is due to the fact that the shorter inspiratory phase of the oscillation may not give the piston enough time to travel to its full deflection.

Since this control affects the symmetry of the oscillatory waveform, it will affect the $\overline{P_{aw}}$ or the ΔP depending on whether the $\overline{P_{aw}}$ Limit control (3) is being used.

6. Frequency

Sets the oscillator frequency in Hertz. The control knob is a 10-turn, clockwise increasing, electrical potentiometer covering the range of 3 to 15 Hertz. The set frequency is displayed on the digital meter.

7. Start/Stop

Manually toggles the oscillator between enabled and disabled. If the green LED on this pushbutton is lit, then the oscillator is enabled and pressing the pushbutton will disable the oscillator. If the green LED is

not lit, then the oscillator is disabled and depressing the pushbutton will enable it to start oscillating—assuming the start up procedure has been properly executed.

This start up procedure is discussed in Chapter 4. If not done properly, the system will not allow the oscillator to start. This prevents the patient from experiencing too high or low a $\overline{P_{aw}}$.

8. Mean Airway Pressure

Displays the $\overline{P_{aw}}$ on a digital meter in cmH_2O.

9. Set Max $\overline{P_{aw}}$

Determines the level in cmH_2O at which the Max $\overline{P_{aw}}$ Exceeded Warning Alarm will be indicated. The Maximum $\overline{P_{aw}}$ level is set by means of a thumbwheel switch covering the range of 0 to 49 cmH_2O. A mechanical stop has been inserted in the tens column of the thumbwheel switch to prevent the dial from being turned past the numeral 4.

The activation of the alarm is indicated by a 3khz modulated tone and a red LED which is adjacent to the thumbwheel switch.

The alarm will reset automatically after correction of the condition. The audible indicator can be silenced for 45 seconds by pushing the 45-Sec Silence pushbutton.

This alarm does not initiate any machine response other than the activation of the visual and audible indicators.

The Maximum $\overline{P_{aw}}$ level set on the thumbwheel switch also determines the point at which the $\overline{P_{aw}}$ < 20% of "Set Max $\overline{P_{aw}}$" Safety Alarm (12) activates. This is explained in detail below.

10. Set Min $\overline{P_{aw}}$

Determines the level in cmH_2O at which the Min $\overline{P_{aw}}$ Exceeded Warning Alarm will be indicated. The Minimum $\overline{P_{aw}}$ level is set by means of a thumbwheel switch covering the range of 0 to 49 cmH_2O. A mechanical stop has been inserted in the tens column of the thumbwheel switch to prevent the dial from being turned past the numeral 4.

The activation of the alarm is indicated by a 3khz modulated tone and a red LED which is adjacent to the thumbwheel switch.

The alarm will reset automatically after correction of the condition. The audible indicator can be silenced for 45 seconds by pushing the 45-Sec Silence pushbutton.

This alarm does not initiate any machine response other than the activation of the visual and audible indicators.

11. $\overline{P_{aw}}$ > 50 cmH_2O

The red LED indicates activation of this preset Safety Alarm. It is also indicated by a 3khzmodulated tone. The alarm is reset only by pushing the Reset pushbutton after the alarm condition has been corrected. The 45-Sec Silence pushbutton can be pushed to silence the audible indicator; however, the red LED indicator will still function and the Dump Valve will remain open.

When this alarm occurs, the Model 3100A will automatically shut down the oscillator, but bias flow will continue. The Dump Valve will be open and will hold the airway pressure to near atmospheric. This protects the patient from the elevated pressure and allows the patient to breathe spontaneously. (See the Patient Circuit section in Chapter 1 for further explanation of this feature.)

Because of the Dump Valve activation, the $\overline{P_{aw}}$ < 20% of "Set Max $\overline{P_{aw}}$" Safety Alarm will also be activated.

After the correction of the condition that triggered the Safety Alarm, the oscillator startup procedure must be followed for reset. This is discussed in Chapter 6.

12. $\overline{P_{aw}}$ < 20% of "Set Max Pa"

The red LED indicates activation of this Safety Alarm. It is also indicated by a 3khzmodulated tone. This alarm triggers at a $\overline{P_{aw}}$ level equal to 20% of the thumbwheel setting of the Set Max $\overline{P_{aw}}$ Warning Alarm (9). The alarm will reset after the alarm condition has been corrected.

The 45-Sec Silence pushbutton can be pushed to silence the audible indicator; however, the red LED indicator will still function.

When this alarm occurs, the Model 3100A will automatically shut down the oscillator, but bias flow will continue. The Dump Valve will open and will hold the airway pressure to near atmospheric. This allows the patient to breathe spontaneously. (See the Patient Circuit section in Chapter 1 for further explanation of this feature.)

After the correction of the condition that triggered the Safety Alarm, the oscillator startup procedure must be followed for reset. This is discussed in Chapter 1.

13. Power Failure

The red LED indicates loss of electrical power or insufficient or inadequate electrical power supply. It is accompanied by a 3khzmodulated audible tone. The following conditions will cause this alarm to trigger:

- Tripping of Model 3100A System circuit breaker.
- Turning off Power Switch (29).
- Power plug being pulled from wall socket.
- Loss of power to the hospital branch line to which the Model 3100A System is connected.
- A failure in the power supply internal to the Model 3100A System.

Once tripped, the alarm indicators (red LED and 3khz modulated tone) can be reset only by pushing the Reset button (14) even if the power failure condition has been corrected. Then, the oscillator Start/Stop Switch must also be pressed to restart the oscillator.

The Power Failure Alarm circuitry is powered by a battery (25) which will be discussed further in the next section covering operation of controls, indicators, and connections on the rear panel of the Control Package.

14. Reset

This momentary pushbutton resets all Safety Alarms and the Power Failure alarm.

The alarm conditions triggering the > 50 cmH_2O and < 20% of "Set Max $\overline{P_{aw}}$" Safety Alarms (11 and 12) must first be corrected before resetting will occur. Since these alarms cause the Dump Valve to open, Reset must be held in with the Start/Stop enabled until the Dump Valve closes and airway pressure builds above the 20% Set Max $\overline{P_{aw}}$ level.

The Power Failure alarm (13) will be reset regardless of whether the alarm condition has been corrected or still exists.

It is normal for the Battery Low LED to light when the reset button is pressed.

15a Battery Low

Indicates the Power Failure alarm battery (25) on the rear panel of the Control Package must be changed as soon as possible to ensure continued proper operation of the Power Failure alarm.

15b Source Gas Low

Indicates the gas pressure at the “Inlet From Blender” or “Air Cooling” connection has fallen below 30 psig.

Since the Battery Low and Source Gas Low are classified as caution alarms, yellow LEDs are used, and there is no audible indicator. These alarms will reset only after the battery has been replaced by a new one or the source gas pressure increases above 30 psig, respectively.

The user should investigate the cause of the alarm. If the problem is a loss in blender output pressure, the Warning or Safety Alarms will soon be activated. If the problem is a loss of oscillator cooling air, the Oscillator Overheated alarm will soon activate. This alarm can occur due to plugging of an Inlet Filter Cartridge with dirt. Refer to the Operator Maintenance section of Chapter 6 for instructions on changing the Inlet Filter Cartridges.

The battery will be discussed further in the next section covering the operation and location of the rear panel controls, indicators, and connections.

16. Oscillator Overheated

Indicates that the oscillator coil is overheated and has reached approximately 175°C. Since this is a Caution Alarm, a yellow LED is used, and there is no audible indicator. This alarm will reset only after the condition has been corrected. The operator should determine if the problem is a loss of, or decrease in, cooling gas pressure. This could be caused by low gas pressure at its source, an occlusion (such as a kinked tube or plugged Inlet Filter Cartridge) or a loose tube connection, internal or external. Refer to the Operator Maintenance section of Chapter 6 for instructions on changing the Inlet Filter Cartridges.

17. Oscillator Stopped

Indicates that the oscillator is enabled (Start/Stop pushbutton green LED lighted) but $\Delta P < 5$ to 7 cmH_2O. A red LED indicator is accompanied by a 3khzmodulated tone. No machine action is taken other than the indicators which automatically reset when the condition is corrected.

18. 45-Sec Silence

Activates and indicates the inhibiting of the audible alarm, for a period of 45 seconds. This control is a lighted pushbutton and indicates a caution with its yellow LED when pushed. Once activated, the 45-Sec Silence cannot be reset, but must time out.

19. Patient Circuit Calibration

Adjusts the maximum mean pressure that can be obtained with a specific Patient Circuit. This screwdriver adjustment is used to calibrate the maximum mean pressure after the Patient Circuit is changed or the $\overline{P_{aw}}$ Control diaphragm is changed. A full setup procedure is detailed in Chapter 6, Maintenance and Troubleshooting.

Rear Panel – Control Package

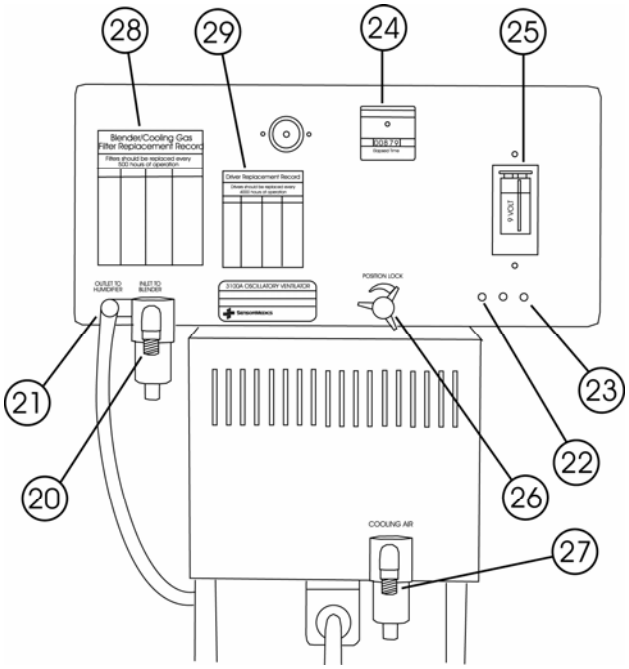

Figure 3.2. Rear Panel Controls, Indicators, and Connections.

The numbers in Figure 3.2 correspond to the following numbered descriptions. A more detailed description of specific design characteristics can be found in Appendix B Specifications.

20. Inlet From Blender

DISS oxygen fitting for connection to an inline Inlet Filter Cartridge and then to the External Air/O2 Blender output. The nominal pressure of the blender output gas should be 50 psig. The Source Gas Low yellow LED will light if the pressure at the inlet drops below 30 psig ±5%.

This input connection is protected from over-pressure by a 75 psig mechanical relief valve. More details regarding this protection are listed in Appendix B.

21. Outlet to Humidifier

Connector which provides bias flow to the inlet of the External Patient Humidifier. This is a 3/8" barbed fitting which is over-pressure protected by a 5 psig mechanical relief valve. The Patient Circuit assembly procedures associated with this connector are discussed in Chapter 2.

22. Pressure Transducer Zero Adjustment

See Chapter 6 Maintenance & Troubleshooting

23. Pressure Transducer Span Adjustment

See Chapter 6 Maintenance & Troubleshooting

24. Elapsed Time Meter

Indicates the total accumulated time in hours that power has been applied to the Model 3100A. Detailed specifications of this meter are given in Appendix B.

25. Power Failure Alarm Battery

A metal cover (fastened by 2 screws) behind which is a 9-volt alkaline battery. The Battery Low LED (15) on front panel indicates when this battery needs to be changed. It can be replaced by any high quality 9-volt alkaline battery.

Note

Remove the 9-volt battery if the instrument is not intended to be used for a lengthy period.

26. Position Lock

This knob locks the Control Package in the rotational position selected by the user. When this lock is turned counterclockwise (unlocked), you are able to turn the Control Package over an arc of nearly 360°. This allows you to view the front panel from an angle independent of the Patient Circuit outlet orientation.

After you have selected the desired position, rotate the knob clockwise to lock the enclosure in position.

Rotation of the knob slightly counterclockwise from fully locked will apply friction to prevent the enclosure from easily being rotated without actually fixing it in place.

More on the subject of positioning of controls is discussed in Chapter 2, Assembly and Installation.

27. Air Cooling Inlet

An Air DISS fitting for connection through an in-line Inlet Filter Cartridge to hospital air supply which provides the oscillator with cooling gas. The nominal pressure of the hospital air should be 50 psig at 15 LPM for 1.5 ohm drivers and 50 psig at 10 LPM for 3.0 ohm drivers. The Source Gas Low yellow LED will light if the pressure at the inlet drops below 30 psig ±5%.

28. Blender/Cooling Gas Filter Replacement

During normal maintenance as described in Chapter 6, record the reading on the Elapsed Time Meter for quick reference.

29. Driver Replacement Record

During normal maintenance as described in Chapter 6, record the reading on the Elapsed Time Meter for quick reference.

System Column and Patient Circuit

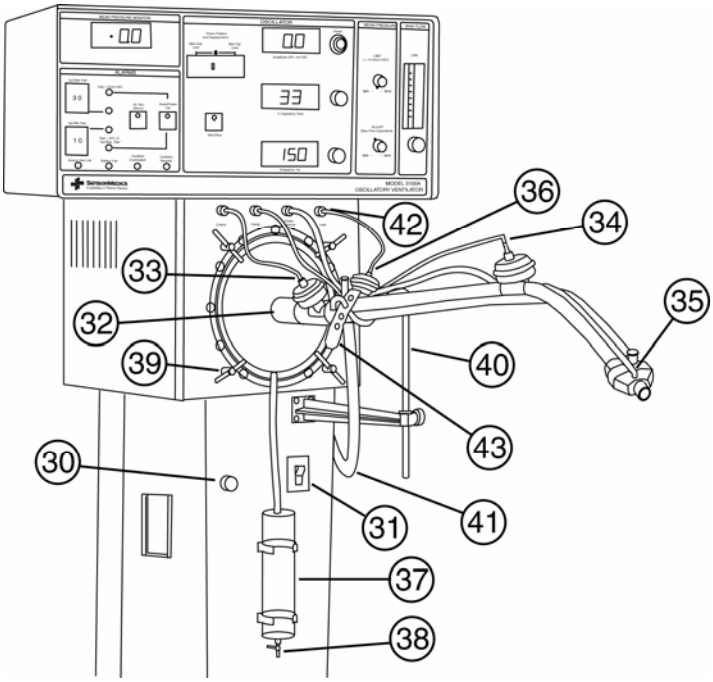

Figure 3.3. System Column and Patient Circuit Controls and Connections.

The numbers shown on Figure 3.3 correspond to the numbers on the following descriptions.

> **CAUTION**
>
> Care should be taken not to crimp or perforate any of the control or sensing lines (running to or from the Patient Circuit) during assembly or operation of the ventilator as this will cause malfunction of the Safety Alarms, Warning Alarms, Caution Alarms, and/or Pressure Limit controls.

30. Piston Centering

Determines the center position of the oscillator piston. This is a 10-turn electrical control with no dial scale marked.

This control adjusts an electrical counterforce on the oscillator piston, which acts in opposition to the $\overline{P_{aw}}$ on the front side of the piston resulting in a centering effect.

As the control is rotated clockwise with constant $\overline{P_{aw}}$, the piston center position is shifted closer to the "Max Exp Limit" on the 17-segment Piston Position and Displacement bar graph. Counter-clockwise rotation of the control shifts the center toward the "Max Insp Limit."

A change in the $\overline{P_{aw}}$ will cause the centering of the piston to shift. To avoid driving the oscillator piston against a mechanical stop, re-center the piston using the Centering Control. Allowing the piston to strike a mechanical stop for an extended period of time could reduce the life of the oscillator mechanism and should be avoided.

Piston Centering will have an effect on ΔP for a given power. Generally speaking, adjustment toward the inspiratory limit reduces the overall volume of the patient circuit and results in a higher ΔP with the

same piston displacement. Conversely, adjustment toward the expiratory limit increases the volume and lowers the ΔP.

Refer to Chapter 4, Operational Verification and Startup Procedures, for instructions regarding the initial setup and functional verification for this control.

31. Power Switch

Turns power to the Model 3100A System on and off. This power switch also functions as a circuit breaker in case of a power overload. If the circuit breaker trips, be sure to locate the problem causing the power overload before resetting the breaker. This switch is a standard rocker switch, which breaks both sides of the power line, as does the built-in circuit breaker.

32. Oscillator Compartment

Attaches to 1 1/4" I.D. inspiratory limb of patient circuit and is held in place by four quarter-turn fasteners.

33. $P\overline{aw}$ Control Valve

A Green Luer bulkhead fitting for connection to green 1/16" I.D. tubing that runs to the control input of the $P\overline{aw}$ Control Valve on the Patient Circuit. Consult assembly procedure in Chapter 2 for details on attachment of this control line to its valve. This line should be replaced periodically during scheduled preventive maintenance of the HFOV.

34. Dump Valve Control

A Red Luer bulkhead fitting for connection to red 1/16" I.D. tubing that runs to the control input of the Dump Valve on the Patient Circuit. Consult the assembly procedure in Chapter 2 for details on attachment of this control line to its valve. This line should be replaced periodically during scheduled preventive maintenance of the HFOV.

35. $P\overline{aw}$ Sense

A White Luer bulkhead fitting for connection to clear 1/8" I.D. tubing that runs to the Airway Pressure Port of the Patient Circuit for the purpose of transmitting the $P\overline{aw}$ signal to the pressure transducer within the Control Package. Consult assembly procedure in Chapter 2 for details on attachment.

36. $P\overline{aw}$ Limit Valve

Blue Luer bulkhead fitting for connection to blue 1/16" I.D. tubing that runs to control input of $P\overline{aw}$ Limit Valve on Patient Circuit. Consult assembly procedure in Chapter 2 for details on attachment of the control line to its valve. This line should be replaced periodically during scheduled preventive maintenance of the HFOV.

37. Water Trap

Condensate should drain into the water trap if the Patient Circuit is positioned properly. There is a small (.025" diameter) hole at the top of the water trap to allow air to escape as it fills.

38. Water Trap Drain

Allows draining of water condensate. Water is drained from the bottom when the stopcock is turned down. The contents of the water trap can be drained while the Model 3100A is still operating as long as the water seal between the ventilator and the bottom drain is not broken. This can be accomplished by always leaving a small amount of water at the bottom of water trap after draining. Follow the instructions in Chapter 6 regarding cleaning and disinfection of water trap and valve mechanisms.

> **CAUTION**
>
> Ensure that the stopcock is closed prior to performing a Patient Circuit Calibration. If the Water Trap Stopcock is left open, Patient Circuit Calibration (39–43 cmH20) may not be achievable, and the deliverable $\bar{P}aw$ will be reduced.

39. Bellows Fastener

Four quarter-turn fasteners that hold the bellows (Oscillator Compartment) in place in front of the oscillator piston.

40. Patient Circuit Cradle

For attachment of Patient Circuit. Refer to Chapter 2 for assembly and adjustment instructions.

41. Humidifier Tubing

The external humidifier is connected between the "Outlet To Humidifier" on the rear of the Control Package and the Bias Flow Inlet on the Patient Circuit. In Figure 3.3, the humidifier tubing is shown connected to the patient circuit without the humidifier inline.

Only the 3/8" tube supplied with the Patient Circuit should be used.

42. Bulkhead Luer Fittings

There are four bulkhead luer fittings on the front of the oscillator compartment for connection to the three valve caps and pressure sense port on the patient circuit.

43. Hold Down Strap

Secures the patient circuit to the Patient Circuit Cradle. This keeps the rigid circuit in a stable, upright position.

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Chapter 4 Operational Verification and Start-up

This chapter covers the proper operational verification and ventilation start-up methods for the Model 3100A HFOV.

See Chapter 2 for instructions on unpacking, assembly, and installation of the Model 3100A HFOV prior to operational start-up and verification.

WARNING
The operational verification and start-up procedure must be followed before ventilation of a patient commences. If at any time during the operational verification and start-up procedure any abnormal function of the Model 3100A HFOV is noted, do not proceed with patient ventilation as this could cause injury or death; contact SensorMedics Technical Support before proceeding any further.

CAUTION

Proper operation of the ventilator must be verified prior to each use. The alarm functions tested in this procedure verify the capability of the device to detect and indicate conditions which could have a harmful effect on the patient.

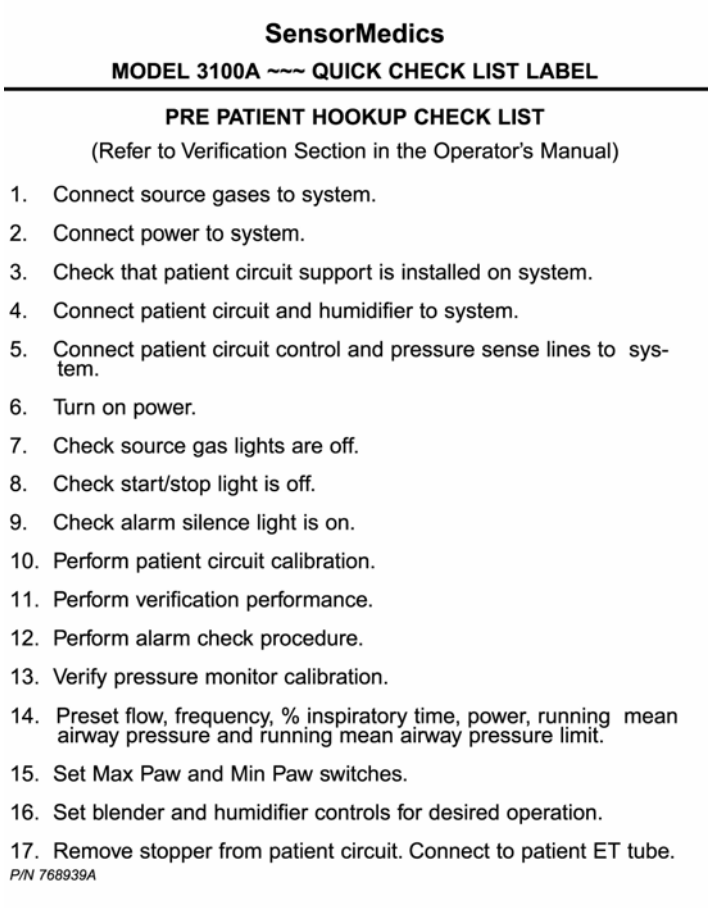
CAUTION

Touch the outer metal cabinet of the instrument before touching any other component to avoid possible instrument component damage from Electrostatic Discharge,

WARNING
Do not operate radio transmitters within 20 feet of this instrument. This may result in erroneous pressure readings leading to false alarms and automatic shut-down.

Start-up Procedures

A "Quick-Checklist" label for pre-patient hookup verification is attached to the ventilator. See figure 4.1 below.



SensorMedics

MODEL 3100A ~~~ QUICK CHECK LIST LABEL

PRE PATIENT HOOKUP CHECK LIST

(Refer to Verification Section in the Operator's Manual)

1. Connect source gases to system.
2. Connect power to system.
3. Check that patient circuit support is installed on system.
4. Connect patient circuit and humidifier to system.
5. Connect patient circuit control and pressure sense lines to system.
6. Turn on power.
7. Check source gas lights are off.
8. Check start/stop light is off.
9. Check alarm silence light is on.
10. Perform patient circuit calibration.
11. Perform verification performance.
12. Perform alarm check procedure.
13. Verify pressure monitor calibration.
14. Preset flow, frequency, % inspiratory time, power, running mean airway pressure and running mean airway pressure limit.
15. Set Max Paw and Min Paw switches.
16. Set blender and humidifier controls for desired operation.
17. Remove stopper from patient circuit. Connect to patient ET tube.

P/N 768939A

Figure 4.1 Quick Check Label

Start-up Procedure

1. Connect the source gases to the Model 3100A HFOV System:
    - Oxygen line to the External Air/O_2 Blender oxygen input fitting
    - Air line to the External Air/O_2 Blender air input fitting and the oscillator "Air Cooling" input connector.
    - External Air/O_2 Blender output to the Control Package rear panel oxygen DISS fitting labeled "Inlet from Blender."
2. Connect Patient Circuit and External Patient Humidifier to the Model 3100A using the assembly procedures described in Chapter 2.

WARNING

Do not attempt to substitute another circuit configuration as this could result in injury to the patient and/or operator or cause equipment damage. The Patient Circuit described in this manual is specifically designed for patient use with the Model 3100A HFOV.

CAUTION

When connecting the Patient Circuit, make certain that it is properly supported by the support arm as described in Chapter 5, Assembly and Installation. Failure to do so could result in inadvertent patient

circuit disconnection due to oscillatory forces or could result in collection of humidifier condensate in the patient airway.

3. Connect all color-coded Patient Circuit Control Lines and the clear Pressure Sense Line to their proper locations on the Patient Circuit as described in Chapter 2.

CAUTION

Care should be taken not to crimp or perforate any of the control or sense lines (running to or from the Patient Circuit) during assembly or operation of the ventilator as this will cause malfunction of the Safety Alarms, Warning Alarms, Caution Alarms, and/or Pressure Limit controls.

4. Block off or obstruct the ET connection port on the Patient Circuit using the #1 rubber stopper accessory provided.
5. Turn on the Main Power Switch (the green LED on the Start/Stop pushbutton should be off). Some of the alarm LED's will be lighted but the 3khzaudible tone will be silenced due to the automatic initiation of the 45-Sec Silence function when power is first turned on. This alarm silence feature can be retriggered during the verification and start-up procedure by pushing the 45-Sec Silence pushbutton.

WARNING

An audible alarm indicates the existence of a condition potentially harmful to the patient and should not go unattended. Failure to respond to alarms could result in injury, including death, to the patient and/or damage to the ventilator.

CAUTION

Ensure that the stopcock is closed prior to performing a Patient Circuit Calibration. If the Water Trap Stopcock is left open, Patient Circuit Calibration (39–43 cmH20) may not be achievable, and the deliverable $\overline{Paw}$ will be reduced.

6. Calibrate the patient circuit to the system. Instructions for this procedure are also located on a label on the side of the Control Package.
   - Turn on source gas pressure and establish Bias Flow at 20LPM at the % oxygen level desired. Be sure to read the flow at the center of the ball, looking level at the flowmeter.
   - Set both Mean Pressure Adjust and Mean Pressure Limit controls to Max (full CW).
   - Push in and hold RESET while observing the Mean Pressure digital readout. It is normal for the Battery Low LED to light when the reset button is pressed.
   - Adjust the Patient Circuit Calibration on the right side of the control package to achieve a $\overline{Paw}$ of 39 to 43 cmH_2O. Do not overturn; if the specified pressure can not be achieved, locate the leak.
   - Release the RESET button; the Battery Low LED should turn off.

CAUTION

Do not over turn the Patient Circuit Calibration screw as this may cause damage to the device. When it is nearing its adjustment limit, it will reach a mechanical stop.

7. Perform the Ventilator Performance Check "Off Patient Only" section. (Instructions for this procedure are also located on a label on the top of the Control Package).
   - Set Frequency to 15, % I-Time to 33, and Power to 0.0.

- Establish Bias Flow at 20 LPM.
- Set the Mean Pressure Limit control to Max (full CW).
- Set the "Set Max $\overline{P_{aw}}$" thumbwheel switch to 30 and the "Set Min $\overline{P_{aw}}$" thumbwheel switch to 10.
- Depress the RESET button long enough to allow $\overline{P_{aw}}$ to increase above 6 cmH2O.
- With the Mean Pressure Adjust control, establish a $\overline{P_{aw}}$ of 19 to 21 cmH2O.
- Depress the START/STOP button to cause the oscillator to run.
- Increase the POWER control setting to 6.0 while simultaneously centering the piston with the Piston Centering control.
- When a stable ΔP reading is obtained with the piston operating in the center portion of its range, verify that the ΔP and $\overline{P_{aw}}$ readings are within the range specified for your corresponding altitude (see Figure 6.1).

8. Depress the START/STOP button to stop the oscillator.
9. With Mean Pressure Adjust and/or Bias Flow adjustment, achieve a mean airway pressure within 2 cmH_2O of the desired level. Ensure that the Bias Flow is sufficient (see Chapter 6).
10. Verify the function of the thumbwheel switches for "Set Max $\overline{P_{aw}}$" and "Set Min $\overline{P_{aw}}$" alarms by setting the Max thumbwheel just below the established mean airway pressure, and by setting the Min thumbwheel just above the established mean airway pressure.
11. Set these thumbwheel alarm switches to their desired settings. This is generally 2–5 cmH_20 above (Max thumbwheel) and below (Min thumbwheel) the established Mean airway pressure.
12. With fingers and thumb(s), squeeze closed the expired limb tubing on the patient circuit to verify operation of the "$\overline{P_{aw}}$ > 50 cmH_2O" alarm.
13. Depress the RESET button until the "$\overline{P_{aw}}$ < 20% of Set Max $\overline{P_{aw}}$" LED is extinguished to reestablish mean airway pressure.
14. Rotate the Mean Pressure Limit control to approximately mid-scale.
15. Again, squeeze the expired tubing on the patient circuit and observe the pressure at which the Mean Pressure display limits. Rotate the Mean Pressure Limit control in the appropriate direction to cause the $\overline{P_{aw}}$ to limit at the desired point.
16. Position the ventilator for connection to the patient. Loosen the Position Lock control and adjust the angle of the Control Package for the best view and access relative to the patient. Retighten the Position Lock.
17. Set the desired % oxygen, mean airway pressure, and ΔP for the patient. ΔP will affect the $\overline{P_{aw}}$ depending on ratio of Flow Rate/$\overline{P_{aw}}$. The lower the ratio, the stronger the effect.

PRECAUTION

Fractional concentration of inspired oxygen should be verified with an oxygen monitor. Administration of excessive oxygen to a patient may be harmful. It is imperative that the prescribed gas mixture is delivered by the blending system.

18. Remove the Patient Circuit stopper. Adjust the External Patient Humidifier to establish the desired gas temperature at the patient airway temperature port. Connect the Patient Circuit to the patient ET tube.

WARNING

Under no circumstances should proximal airway gas temperature of 41°C be exceeded. This could result in injury to the patient's upper airway membranes.

CAUTION

When the ventilator is connected to a patient, it is imperative that someone be in attendance at all times in order to react to any alarms and to detect other indications of a problem.

19. Push the Reset pushbutton until the "$\overline{Paw}$ < 20% of Set Max $\overline{Paw}$" LED is extinguished to reestablish mean airway pressure.
20. Set the Power control for the desired ΔP (see Chapter 5).
21. Adjust the Piston Centering control to keep the piston approximately centered and away from the mechanical stops at "Max Insp Limit" and "Max Exp Limit" as indicated on the Piston Position and Displacement display.
22. Readjust the Frequency, % Inspiratory Time, Power, Mean Airway Pressure, Bias Flow, and Piston Centering controls as needed during patient ventilation.

WARNING

Under no circumstances should the ventilator be used in the presence of flammable anesthetics due to the possibility of explosion.

CAUTION

Do not place on the Control Package of the ventilator any fluid-containing accessories, accessories that weigh more than 10 pounds or accessories that extend more than six inches above the ventilator electronics package or beyond its sides. This could cause the ventilator to tip over, resulting in patient or user injuries and/or damage to the equipment.

Performance Verification

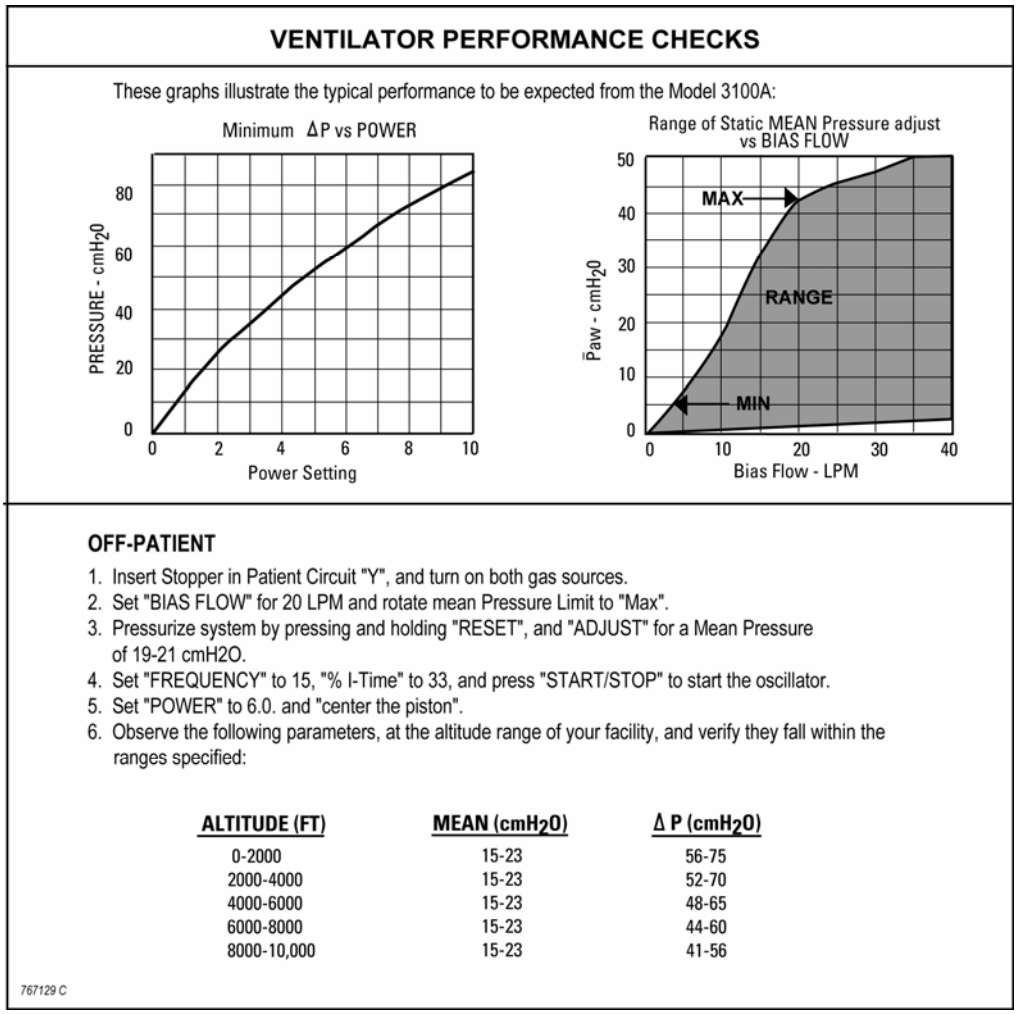

VENTILATOR PERFORMANCE CHECKS
These graphs illustrate the typical performance to be expected from the Model 3100A:
Minimum ΔP vs POWER
PRESSURE - cmH2O
Power Setting
Range of Static MEAN Pressure adjust vs BIAS FLOW
MAX
RANGE
MIN
P̄aw - cmH2O
Bias Flow - LPM
OFF-PATIENT
1. Insert Stopper in Patient Circuit "Y", and turn on both gas sources.
2. Set "BIAS FLOW" for 20 LPM and rotate mean Pressure Limit to "Max".
3. Pressurize system by pressing and holding "RESET", and "ADJUST" for a Mean Pressure of 19-21 cmH2O.
4. Set "FREQUENCY" to 15, "% I-Time" to 33, and press "START/STOP" to start the oscillator.
5. Set "POWER" to 6.0. and "center the piston".
6. Observe the following parameters, at the altitude range of your facility, and verify they fall within the ranges specified:
ALTITUDE (FT) MEAN (cmH2O) Δ P (cmH2O)
0-2000 15-23 56-75
2000-4000 15-23 52-70
4000-6000 15-23 48-65
6000-8000 15-23 44-60
8000-10,000 15-23 41-56
767129 C

Figure 4.1. Ventilator Performance Checks.

The two graphs shown in Figure 4.1 are intended to guide the operator in setting Power, Mean Pressure Adjust, and Bias Flow controls, and to help ascertain that the 3100A is performing in a typical fashion without problems.

The left graph indicates the approximate setting of the Power control required to achieve a specific ΔP pressure. The right graph illustrates the Bias Flow required to achieve a range of Mean pressures with the single-turn Mean Pressure Adjust control.

When establishing a specific mean airway pressure, you must find the required Bias Flow that will allow the mean pressure to be adjusted above and below that desired. Set the Mean Pressure Adjust control to approximately “twelve o'clock” and set the Bias Flow as indicated on the graph, to a level which puts the desired $\bar{P}aw$ level in its mid-range. When the system is operating, whether ON or OFF Patient, the settings of the controls relative to the pressures being developed and displayed, will quickly give an indication that the system performance is nominal.

Chapter 5 Clinical Guidelines

Treatment Strategies

The clinical guidelines described in this chapter reflect the treatment strategies developed by Dr. Robert deLemos and his colleagues at Wilford Hall Medical Center, Lackland Air Force Base, Texas. Their early work with premature baboons was followed by refinement of the strategies during the course of treating hundreds of neonates with a broad spectrum of lung diseases. The basic strategies outlined here were adopted and subsequently validated in Multi-Center Controlled Trials.

The pediatric strategies were developed during a prospective randomized controlled trial in pediatric ARDS. These strategies are suggested approaches only and there may be other approaches which can be equally beneficial.

For the randomized controlled trial, "failing on conventional ventilation" was defined as a ventilated patient with an oxygen index ($100 \times FIO_2 \times MAP/PaO_2$) greater than 13 in two arterial blood gases sampled during a six hour period.

The prospective randomized trial of the 3100A in children included mostly patients weighing less than 20 kg. While the study also demonstrated the ability to ventilate and oxygenate children up to 30 kg, these isolated results were not significant in number. The age range of pediatric patients treated with the 3100A in this trial was up to 11 years of age and up to 16 years of age in reported rescues

Adjusting the 3100A controls to execute treatment strategies

The treatment strategies outlined here are easy to implement because, for most clinical situations, only two of the 3100A's six controls are routinely adjusted. These are:

- mean airway pressure and
- oscillatory pressure amplitude (ΔP).

The other four controls,

- Bias Flow,
- Piston Centering,
- Frequency and
- % Inspiratory Time,

are rarely changed during the course of treatment, as explained below.

Bias Flow

For the 3100A, a continuous flow of fresh, humidified gas from a neonatal/pediatric humidifier and air/oxygen blender is required to replenish oxygen and remove carbon dioxide from the patient circuit. Beyond a minimum sustenance level, more bias flow has neither a positive nor a negative effect upon oxygenation, although changes in Bias Flow cause changes in $\overline{Paw}$. In practice the following settings are usually appropriate:

Premature	10-15 lpm	Small Child	15-25 lpm
Near-term	10-20 lpm	Large Child	20-30 lpm

If high oscillatory amplitudes are prescribed (proximal ΔP >70cmH_20), bias flow should be increased to ensure that the patient circuit clearance flow is greater than the patient's oscillatory flow. If the bias flow is inadequate, the patient circuit's *effective* dead space increases. This diminishes the ventilation effect of increasing the oscillatory amplitude (ΔP).

If signs of carbon dioxide retention persist, increase the bias flow in increments of 5 lpm as frequently as every 15 minutes. Remember as you do this, that the $\overline{Paw}$ Adjust control will have to be turned counterclockwise to maintain the desired $\overline{Paw}$.

Piston Centering

The natural resting position of the oscillating piston is in the center of the one-inch long cylindrical space that contains it. If displaced off-center in either direction, the maximum oscillatory motion which can be produced will be limited by the closer of the two mechanical stops at the front and back walls of this cylinder. The Piston Centering control is used to maintain this centered position. It works by applying an adjustable direct current to the oscillator coil. This creates an opposing force to counterbalance the various levels of mean airway pressure to which the front of the piston, the patient side, may be exposed. Because any changes in settings can affect the position of the piston, the piston should be adjusted and centered as necessary. By not centering the piston, this could lead to damage to the coils on the piston and can decrease the life of the driver. If the unit is on maximum settings, it may not be possible to center the piston due to the distortion of the signal from the indicator on the back of the piston. By attempting to center the piston during this distortion, it may cause the piston be extremely off center and lead to damaged coils.

Frequency

For most therapeutic situations a frequency range of 10-15 Hz has been found to be effective for both premature and near-term patients. In practice, as patient weight increases, starting frequency is decreased. Frequencies between 6-10 Hz are common in children, with lower frequencies more typically used for larger children.

Most of the time the frequency control remains unchanged throughout the therapy. The exceptional cases which respond better when the frequency is lowered will be addressed later.

% Inspiratory time

For most therapeutic situations a % inspiratory time of 33% has been found to be very effective. Most of the time this control remains at 33% throughout the therapy. There are exceptional cases which respond better when the % inspiratory time is gradually increased toward 50%.

FiO2

The basic strategy employed with the 3100A for the adjustment of inspired oxygen concentration (FIO_2), is the same as in conventional ventilator strategy, which is to wean the concentration lower, as tolerated.

Mean Airway Pressure and Oscillatory Pressure Amplitude

These two controls are at the heart of the strategy for patient management with the 3100A.

Mean Airway pressure ($\overline{Paw}$) - Mean airway pressure changes are accomplished by a single-turn control which varies the inflation of a mushroom valve. The valve then partially blocks the exit of the bias flow from the expiratory limb of the patient circuit causing an increasing in mean pressure. The

management of mean airway pressure is fundamental to controlling oxygenation. Increases in mean airway pressure increase lung volume and therefore alveolar surface area. At any given level of oscillatory pressure amplitude (ΔP), oxygenation is improved by increasing the mean airway pressure, and vice versa. Disease-specific strategies for the manipulation of mean airway pressure are described below.

$P\overline{aw}$ will show small fluctuations with temperature and humidity changes. The operator should be ready to make minor adjustments to $P\overline{aw}$ as the circuit temperature rises and falls (for instance, when a humidifier canister is filled with fresh water).

Oscillatory Pressure Amplitude - Changes in the oscillatory pressure amplitude (ΔP) are accomplished with the ten-turn "Power" control. This control adjusts the electrical current level applied to the driving coil of the linear motor that displaces the diaphragm-sealed piston. As the piston is displaced rapidly forward and backward in a nearly square-wave pattern by the square-wave current in the driving coil, high-amplitude pressure fluctuations (also approximately square-wave shaped) are symmetrically superimposed on the level of mean airway pressure previously established in the patient circuit as described above (at an %Insp Time of 50%).

Although the 3100A is capable of generating oscillatory pressure as high as 90 cmH_20 peak-to-peak at the proximal endotracheal tube attachment point of the patient-circuit wye, no such pressures are developed in the trachea, because the respiratory system impedance (of which the endotracheal tube is the dominant element) greatly attenuates these high frequency pressure waves and at the same time distorts their waveform into a nearly triangular pattern. For instance, at 15 Hz and a compliance of 1 ml/cmH_2O, the losses are:

90%	2.5 mm ET tube
80%	3.5 mm ET tube
60%	4.5 mm ET tube
47%	5.5 mm ET tube
34%	6.5 mm ET tube

Hence, in the clinical setting a larger ET tube will result in greater distal pressure waveforms and a greater reduction in arterial PCO_2.

To further clarify this oscillatory pressure amplitude phenomenon, consider the following example:

A neonate with a compliance of 1 ml/cmH_2O is attached to the 3100A's patient circuit with a 2.5 mm ET tube.

The 3100A is operating at 15 Hz, 33% Inspiratory Time, a mean airway pressure of 25 cmH_2O and a ΔP of 60 cmH_2O, hence the peak proximal airway pressure has a peak of 55 cmH_2O and a low of -5 cmH_2O. The tracheal airway pressure has a peak of approximately 28 cmH_2O and a low of 22 cmH_2O because of the 90% attenuation caused by this size ET tube at 15 Hz.

With the 1 ml/cmH_2O compliance, this distal ΔP of 6 cmH_2O creates a high-frequency tidal volume of 6 ml in a lung held at a nearly-constant, well-inflated level by the 25 cmH_2O mean airway pressure.

At a given mean airway pressure and frequency, the sole mechanism by which ventilation (carbon dioxide removal) is achieved is the high-frequency tidal volume created by the oscillatory pressure swings (ΔP). Hence, as the "Power" control is increased, the piston displacement increases, the ΔP increases, the tidal volume increases, and ventilation increases.

Although the great majority of neonates and children can be ventilated with this straightforward method of adjusting ΔP upwards to counter a high $PaCO_2$ level, there are some patients who require an even larger ΔP.

When this is the case, the strategy is to take advantage of the frequency-dependent nature of the attenuation caused by the ET tube. As the frequency is reduced, the attenuation diminishes and a larger distal ΔP occurs, resulting in an increase in delivered tidal volume. Reducing the frequency from 15 Hz to 10 Hz, in 1 Hz increments, is generally sufficient to control persistently high $PaCO_2$ levels in neonates, but a few instances have occurred wherein the frequency had to be reduced in 1 Hz increments to 5 Hz. In extremely rare instances, the frequency had to be reduced to 3Hz.

Lower frequencies are commonly used in larger children.

Therapeutic Objectives

Assuming that peak alveolar pressure is the causative factor in airway rupture, the principle advantage of HFOV over conventional ventilation is its ability to maintain adequate ventilation and oxygenation at lower peak alveolar pressures.

Because ventilation is readily achieved with relatively low oscillatory pressure amplitudes, patients can be managed at higher mean airway pressure while simultaneously operating at lower peak alveolar pressures than conventional ventilators. This improves oxygenation by increasing alveolar/saccular recruitment and reinflation of atelectatic lung spaces, thereby improving ventilation/perfusion matching. The therapeutic objectives in using the 3100A are to take maximum advantage of these unique characteristics.

General Aspects of Clinical Strategy

Although there are some variations in strategy that are disease-specific, the general aspects of managing patients with the 3100A are the same for all the forms of lung disease for which it has been shown to be effective. This strategy is a suggested approach only; other approaches may be equally beneficial.

Special Considerations in Larger Children

CAUTION

Patient weight is an important guide to lung volume and anatomical dead space, as well as the metabolic demand placed on ventilation. While the maximum displacement of the 3100A is approximately 365 ml, the actual volume delivered to the patient depends on the power setting, frequency, endotracheal tube size, and patient respiratory system compliance. Therefore special attention should be given to ventilatory requirements and $PaCO_2$ in larger children.

The performance charts in Appendix B of this manual can be used as a guide to these relationships, but they may vary somewhat with individual patients and instruments.

Ventilation

1. Primarily manage ventilation (carbon dioxide removal) by adjusting the oscillatory pressure amplitude (ΔP). Increasing ΔP improves ventilation. At initiation of therapy, adjust ΔP just high enough to produce perceptible chest wall motion.
2. If maximum ΔP is unable to sufficiently improve ventilation, employ the secondary strategy of reducing the frequency to take advantage of reduced ET tube attenuation at lower frequency increasing delivered tidal volume.
3. If elevated $PaCO_2$ still persists, resume frequency reduction. A low of 3 Hz will usually be sufficient.

4. If elevated $PaCO_2$ still persists, obtain up to a 10% increase in high frequency tidal volume by increasing the % Inspiratory Time toward 50%.

Oxygenation Management

1. Primarily manage oxygenation by maintaining $\overline{Paw}$ at the level necessary to obtain satisfactory pulmonary inflation (typically 10 percent to 30 percent higher than the level used on the conventional ventilator). A chest x-ray which reveals nine posterior ribs above the level of the diaphragm has been used as an indication of satisfactory inflation. If lung compliance subsequently improves, it will be necessary to reduce $\overline{Paw}$ to avoid lung over-inflation. The exception to utilizing higher $\overline{Paw}$ to normalize alveolar surface area is air leak syndrome. Here it is prudent to accept $\overline{Paw}$ similar to conventional ventilation (lower lung volume) and utilize higher FIO_2.
2. Place priority on weaning FIO_2 to less than 0.6 before weaning to lower mean airway pressures. Once FIO_2 is less than 0.6, shift emphasis to weaning mean airway pressure lower, while still maintaining normal lung inflation and PaO_2.

Weaning

Wean to conventional ventilation when all the following conditions have been satisfied:

1. Pneumothoraces and/or pulmonary interstitial emphysema (PIE) have resolved, if present.
2. Mean airway pressure has been weaned to the 6–12 cmH_2O range.
3. ΔP has been weaned to less than 30 cmH_2O.
4. Arterial blood gases have been stabilized in the following ranges:

   pH = 7.25–7.45

   PaCO2 = 35–50

   PaO2 = 50–80

Mean and Range of 3100A Settings

In order to impart a better appreciation for mean values and ranges of control settings on the 3100A to be expected during clinical use, the chart below summarizes the experience of the neonatal and pediatric Multi-Center Trials.

Mean and Range of 3100A Settings from Multi-center Study

TIME	FIO2	FREQUENCY	$\overline{Paw}$	**Δ**P	% IT
At Start	.85 (.53–1.0)	15 (10–15)	17 (11–35)	45 (26–75)	33 (33–33)
During Treatment	.81 (.3–1.0)	15 (4–15)	15 (6–35)	41 (11–80)	33 (33–50)
At Weaning	.30 (.22–.41)	15 (15–15)	10 (7–19)	31 (10–43)	33 (33–33)

Summary of HFOV Treatment Strategies

As an additional aid to executing these ventilation and oxygenation strategies, the chart used in the Multi-Center Trials is reproduced below.

Summary of HFOV Therapeutic Intervention and Rationale

Clinical Indicators	Therapeutic Intervention	Treatment Rationale
FIO2 above .60		
High PaCO2 with:		
PaO2 = okay	Increase ΔP	Increase ΔP to achieve optimal PaCO2
PaO2 = low	Increase $\overline{P_{aw}}$, ΔP, FIO2	Adjust $\overline{P_{aw}}$ and FIO2 to improve O2 delivery
PaO2 = high	Increase ΔP, decrease FIO2	Decrease FIO2 to minimize O2 exposure
FIO2 above .60		
Normal PaCO2 with:		
PaO2 = okay	No action	No action
PaO2 = low	Increase $\overline{P_{aw}}$, FIO2	Adjust $\overline{P_{aw}}$ and FIO2 to improve O2 delivery
PaO2 = high	Decrease FIO2	Decrease FIO2 to minimize O2 exposure
FIO2 above .60		
Low PaCO2 with:		
PaO2 = okay	Decrease ΔP	Decrease ΔP to achieve optimal PaCO2
PaO2 = low	Increase $\overline{P_{aw}}$/FIO2, decrease ΔP	Adjust $\overline{P_{aw}}$ and FIO2 to improve O2 delivery
PaO2 = high	Decrease FIO2, ΔP	Decrease FIO2 to minimize O2 exposure
FIO2 below .60		
High PaCO2 with:		
PaO2 = okay	Increase ΔP	Increase ΔP to achieve optimal PaCO2
PaO2 = low	Increase FIO2, increase ΔP	Increase FIO2 to improve PaO2
PaO2 = high	Increase ΔP, decrease $\overline{P_{aw}}$	Decrease $\overline{P_{aw}}$ to reduce PaO2
FIO2 below .60		
Normal PaCO2 with:		
PaO2 = okay	No action	No action
PaO2 = low	Increase FIO2	Increase FIO2 to improve PaO2
PaO2 = high	Decrease $\overline{P_{aw}}$, FIO2	Decrease $\overline{P_{aw}}$ and FIO2 to reduce PaO2
FIO2 below .60		
Low PaCO2 with:		
PaO2 = okay	Decrease ΔP	Decrease ΔP to achieve optimal PaCO2
PaO2 = low	Increase FIO2, decrease ΔP	Increase FIO2 to improve PaO2
PaO2 = high	Decrease $\overline{P_{aw}}$, decrease ΔP	Decrease $\overline{P_{aw}}$

Disease-Specific Variations to General Clinical Strategies

Homogeneous Lung Disease Without Significant Air Leak

The primary pulmonary diagnoses which are associated with this pattern of lung disease are: pneumonia and respiratory distress syndrome.

For these diagnoses, follow the general strategies outlined previously in this chapter.

Non-Homogeneous Lung Disease, Air Leak Syndromes and Airway Disease

The primary diagnoses in this group of illnesses are: meconium aspiration syndrome, pulmonary interstitial emphysema (PIE), and severe recurrent pneumothoraces. The major pathophysiologic processes are: persistent leak of gas from the airways and alveoli into the interstitium of the lung or into the pleural space, and trapping of gas within the lung.

For these diagnoses, also follow the general strategies outlined above, but with the following important changes in emphasis and pressure levels:

- a. When FIO_2 is above 0.6, place equal emphasis on weaning mean airway pressure lower, even if it means accepting higher $PaCO_2$ levels and lower PaO_2 levels (especially in premature patients), in order to further reduce the peak inflation pressure and, thus, the risk of trapping and recurrent air leak.
- b. Initiate therapy at a lower frequency (typically 6–10 Hz) to provide a longer expiratory time and, thus, further reduce the risk of gas trapping.

Adverse Effects

High frequency ventilation, as with conventional positive pressure ventilation, has inherent risks in this patient population. These possible adverse effects include: under/over ventilation, under/over humidification, intraventricular hemorrhage (IVH), bronchopulmonary dysplasia (BPD), necrotizing tracheal bronchitis (NTB), atelectasis, hypotension, pneumothorax, pneumopericardium, pneumomediastinum, pneumoperitoneum, and pulmonary interstitial emphysema (PIE).

CAUTION

Follow closely the recommendations contained in this Chapter regarding the use of chest radiographs and cerebral ultrasound to monitor patient condition. During HFOV, as with all ventilators, the relationship between improvement in lung compliance, inadvertent increases in lung volume, increased pleural pressure, and decreased venous return is a matter of concern, since it may result in decreased cardiac output and a possible increase in the risk of IVH in neonates.

WARNING

Sudden unexplained bradycardic events associated with no other clinical changes are possible in neonates who are being weaned or close to being weaned from HFOV therapy. These events may signal possible rapid improvements in patient lung compliance with overdistention during HFOV therapy and may require rapid weaning of $\overline{Paw}$ or switching to conventional ventilation.

CAUTION

The patient's $tcPCO_2$ and $tcPO_2$ or SpO_2 must be monitored continuously to insure that blood gases are at the proper level. It is important that an unrestricted and unobstructed patient airway be maintained during HFOV. To insure a patient airway, always maintain proper suctioning procedures as described in the Suctioning Guidelines Section of Chapter 5, Clinical Guidelines. Since only proximal airway pressure is monitored, no alarm will occur in the event of an obstruction or restriction.

Recommended Monitoring Frequency

Recommended frequency for monitoring key pulmonary status parameters is as follows:

Arterial Blood Gases

a. Every 45–60 minutes immediately following initiation of HFOV therapy to correlate to transcutaneous values.

b. Every 2 hours for a period of 8 hours

c. Every 4 hours for a period of 16 hours

d. Every 8–12 hours depending on institution policy during continuation of treatment

Note: Arterial Blood Gas Values should be checked within 1 hour after a major setting change, or as clinically indicated

Non-Invasive Blood Gases (tcPO2, tcPCO2 and SpO2)

Non-invasive blood gas values should be checked continuously. This is particularly important in larger children who have more dead space and a greater metabolic demand on ventilation.

Chest X-ray

a. Within 4 hours of initiation of HFOV.

b. Every 12 hours for the next 24 hours

c. Every 24 hours for the next 5 days

d. Every 48 hours for the next 8 days

e. Every week thereafter during continuation of HFOV, or as clinically indicated.

f. Whenever lung over inflation is suspected

Cerebral Ultrasound

One initially in neonates after the onset of treatment, then as needed. Cerebral ultrasounds are generally not indicated in children.

Suctioning Guidelines

The need to suction during HFOV use should be determined based on institution policy and clinical signs, just as with Conventional Ventilation (CV). The Multi-Center Studies found no difference in the

frequency of suctioning between the HFOV and CV patients. However, some have observed that more frequent suctioning becomes indicated during the treatment of the sickest infants, especially after they have stabilized.

A closed in-line suction system or a suction adapter may be used if it does not interfere with the function of the $P_{\overline{aw}}$ alarm. See CAUTION below.

CAUTION

Do not use extraneous ventilator circuit attachments (such as a suction port) without a secondary external alarm capable of detecting ventilator disconnection. Due to their inline pressure characteristics such attachments could possibly keep the $P_{\overline{aw}}$ alarm from detecting an accidental ventilator circuit disconnection.

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Chapter 6 Maintenance & Troubleshooting

This chapter covers the Model 3100A maintenance and troubleshooting procedures with which the operator and service technician should be acquainted.

SensorMedics or its official representative will make available upon request such circuit diagrams, component part lists, descriptions, calibration instructions or other information to assist ***Factory-Qualified*** technical personnel to repair those parts of the equipment which are classified as repairable. If you are interested in factory training, please contact the SensorMedics Service Department for scheduling and pricing of our biomedical training classes.

WARNING
Failure to comply with the recommended maintenance procedures described in this chapter could result in injury to the patient or operator or could result in damage to the equipment.

Exterior Cleaning

When surface cleaning of the 3100A is desired, we recommend using a weak disinfectant liquid to wipe down the exterior of the instrument. Do not spray liquid cleaners directly on the exterior surface; spray the cleaning cloth and wring it nearly dry before wiping.

CAUTION

Do not allow liquids to drip into the instrument.

Note

Do not use alcohol or sterilization liquids on the exterior surface of the 3100A, including the driver diaphragm.

Do not use abrasive cleaners or solvents on the exterior surface of the 3100A, including the driver diaphragm.

Operator Maintenance Procedures

The Operator is responsible for the following maintenance procedures:

- Emptying the Water Trap.
- Changing the Compressed-gas Inlet Filter Cartridge Elements.
- Changing the Power Failure Alarm battery.
- Cleaning the Column Lint Filter.
- Changing the Patient Circuit.

Emptying the Water Trap

The Water Trap must be emptied as described below.

CAUTION

The Water Trap must be drained at intervals. If the ventilator is operating, leave a small amount of water at the bottom of the Water Trap container to act as a flow and pressure seal between the ventilator and the output of the drain.

To open the drain valve, rotate it downwards. Empty the contents of the water trap into a disposable cup, or a container which can be subsequently disinfected.

When the Model 3100A is not operational, the Water Trap container can be completely emptied.

CAUTION

Ensure that the watertrap stopcock is closed prior to performing a Patient Circuit Calibration. If the stopcock is left open, Patient Circuit Calibration (39–43 cmH_20) may not be achievable, and the deliverable $\overline{P}aw$ will be reduced.

Changing the Compressed Gas Inlet Filter Cartridge Elements

The 0.1 micron Inlet Filter Cartridges are placed at the input of both the Inlet From Blender DISS oxygen fitting and the Air Cooling Inlet DISS air fitting. Their purpose is to capture any dirt particles or moisture before entry into the Model 3100A HFOV.

CAUTION

The Inlet Filter Cartridges for the blended gas and the air inputs to the ventilator must be replaced at least every 500 hours of operation as described in this chapter. Failure to replace a Filter Cartridge or substitution of an unauthorized cartridge could result in injury to the patient and/or damage to the equipment. Use only SensorMedics cartridges (P/N 767163 box of 10).

The recommended minimum change interval is every 500 hours of operation. However, the level of contaminants in the gas lines of your hospital may be higher than normal. If the Model 3100A HFOV is used for the first time at a new location within your hospital, Filter Cartridges should be checked for flow-limiting contaminants after 100 hours of operation, and then after 300 hours of operation, to determine whether or not a 500 hour change interval is appropriate.

A Filter Cartridge which has been allowed to accumulate flow limiting contaminants will cause the gas supply pressure at the particular DISS fitting to drop. Eventually, the Source Gas Low alarm will trigger. Refer to Chapter 3 for a description of this alarm indication.

The procedure for changing a cartridge is as follows:

1. Turn off and disconnect both the air and oxygen source gas lines.
2. Unscrew body of inlet filter.
3. Remove old cartridge.
4. Install new cartridge. Two spare cartridges are shipped with the 3100A ventilator.
5. Screw filter back together.
6. Record the Elapsed Time Meter reading on the Filter Replacement Record label attached to the rear of the 3100A (see figure 6.1)

BLENDER COOLING GAS FILTER REPLACEMENT RECORD

Filters should be replaced every 500 hours of operation.

REPLACED	REPLACED	REPLACED	REPLACED
_____ Hrs	_____ Hrs	_____ Hrs	_____ Hrs
_____ Hrs	_____ Hrs	_____ Hrs	_____ Hrs
_____ Hrs	_____ Hrs	_____ Hrs	_____ Hrs
_____ Hrs	_____ Hrs	_____ Hrs	_____ Hrs
_____ Hrs	_____ Hrs	_____ Hrs	_____ Hrs
_____ Hrs	_____ Hrs	_____ Hrs	_____ Hrs
_____ Hrs	_____ Hrs	_____ Hrs	_____ Hrs
_____ Hrs	_____ Hrs	_____ Hrs	_____ Hrs
_____ Hrs	_____ Hrs	_____ Hrs	_____ Hrs
_____ Hrs	_____ Hrs	_____ Hrs	_____ Hrs

P/N 767159 A

Figure 6.1 Filter Replacement Record

> **CAUTION**
>
> The filter cartridge body must be screwed back on securely. Cross-threaded or loose installation will result in leaks and possible dislodging of the cartridge body. If the cartridge body is dislodged, it will cause the ventilator to cease functioning.

Changing the Power Failure Alarm Battery

When the yellow Battery Low LED on the front panel of the Control Package is lit, the Power Failure Alarm battery should be changed as soon as possible. Access to this battery is gained through the access door on the rear panel. A good quality 9 volt alkaline battery should be used (see figure 6.3).

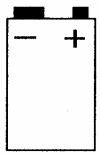


Figure 6.2

Orientation of the battery is indicated by the Battery Attachment Label (see figure 6.2)

Figure 6.3

Cleaning the Column Lint Filter

After each patient, inspect and clean the lint filter in the Column of the Model 3100A HFOV. Remove the filter element from its holder on the column rear. Shake dirt out, wash it in warm sudsy water, dry it out and replace it in the holder. Failure to perform this procedure will eventually cause a significant restriction of air cooling flow to the oscillator squarewave driver. This could lead to overheating of the driver and eventual malfunction of the oscillator.

Changing the Patient Circuit

Change the Patient Circuit as often as required by your institution's policy for conventionally-ventilated patients. Dispose of the three snap-off Cap/Diaphragms and the Bellows/Water Trap Assembly; ***these items absolutely cannot be reused***. The Patient Circuit Body is recommended for single use. If you

wish to re-use the Patient Circuit Body, follow your institution's standard method for disinfecting plastic parts of ventilator circuits.

> **CAUTION**
>
> The Patient Circuit Body is constructed of acrylic, polycarbonate, and polyvinyl chloride (PVC) plastics. DO NOT USE any disinfecting solutions that can damage these components. Carefully check the specifications of any disinfecting solutions before using.

Patient Circuit Calibration

Before use on a patient, each patient circuit must be calibrated to the Model 3100A by following the procedure shown on the Patient Circuit Calibration Label below.:

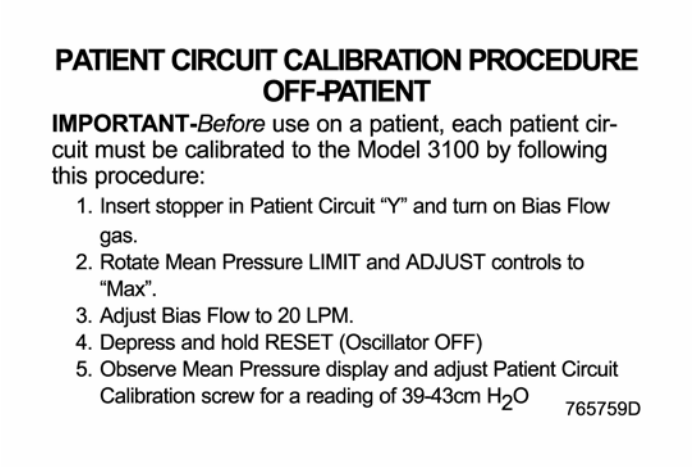

PATIENT CIRCUIT CALIBRATION PROCEDURE
OFF-PATIENT
IMPORTANT-Before use on a patient, each patient circuit must be calibrated to the Model 3100 by following this procedure:
1. Insert stopper in Patient Circuit "Y" and turn on Bias Flow gas.
2. Rotate Mean Pressure LIMIT and ADJUST controls to "Max".
3. Adjust Bias Flow to 20 LPM.
4. Depress and hold RESET (Oscillator OFF)
5. Observe Mean Pressure display and adjust Patient Circuit Calibration screw for a reading of 39-43cm H_2O
765759D

Figure 6.4 Patient Circuit Calibration label

> **CAUTION**
>
> Do not over turn the Patient Circuit Calibration adjustment screw as this may cause damage to the device. When it is nearing its adjustment limit, it will reach a mechanical stop.

Other Scheduled Periodic Calibration

There are three other functions within the Model 3100A HFOV which require periodic calibration:

1. Control Package DC Power Supply.
2. Airway Pressure Monitor Transducer Calibration.
3. Piston Position and Displacement Display.

Maintenance of accurate calibration of these functions is extremely important to the proper function of the Model 3100A HFOV. If at any time, a calibration discrepancy exists that cannot be solved by the normal calibration procedures described below, do not attempt to treat a patient with the HFOV. Call SensorMedics immediately for assistance.

The calibration interval for these functions is tracked on the Elapsed Time Meter (24) on the Rear Panel of the Control Package. A calibration must be performed at least every 2,000 hours or when a discrepancy is noticed. An National Institute of Standards and Technology traceable digital voltmeter

and pressure measurement transducer are required for proper calibration of the Power Supply and the Airway Pressure Monitor.

To assure accurate setup, all periodic calibrations must be done with the Model 3100A HFOV at room temperature and prior to extensive operation of the oscillator. If the oscillator is warm due to previous operation, allow a non-operating cool down interval of at least one hour before commencing calibration.

CAUTION

The cover enclosing the Control Package, Column, or any other portion of the ventilator must not be removed by the user. To avoid electrical shock hazard, please refer all service requiring cover removal to a qualified biomedical equipment service technician.

Control Package DC Power Supply Calibration

The calibration procedure for the Control Package DC Power Supply is as follows:

1. Turn off Power to the 3100A HFOV and unplug unit from AC receptacle.
2. Remove the rear column cover.
3. Plug the 3100A HFOV back into receptacle and turn on Power.
4. Refer to figures 6.5 and 6.6 to verify which 5/15V Power Supply has been installed in the 3100A HFOV. The Power Supply is located immediately below the oscillator drive electronics.

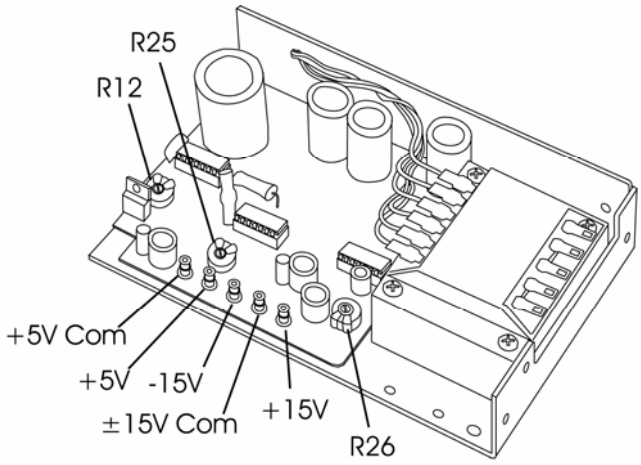


Figure 6.5. Power Supply Adjustment Potentiometers.

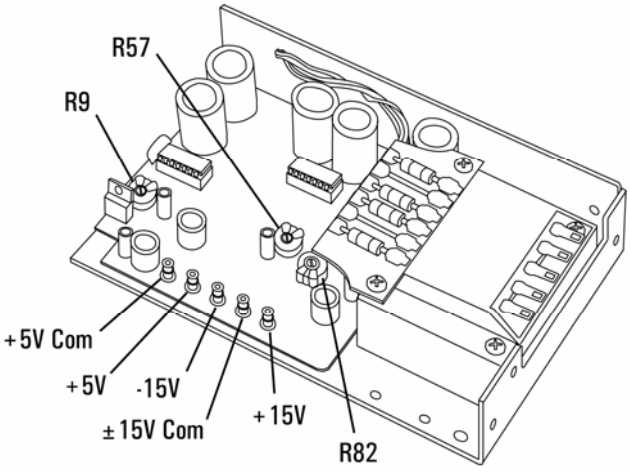


Figure 6.6 Power Supply Adjustment Potentiometers

5. Connect the negative lead of a digital voltmeter to the +5V Com terminal of the DC Power Supply.
6. Connect the positive lead of the digital voltmeter to the +5V terminal of the DC Power Supply.

Note

If adjustments are necessary, first remove the front column cover.

7. If necessary, adjust R12/R9 for a reading of +5 volts ±0.25 volts on the digital voltmeter.
8. Connect the negative lead of the voltmeter to the ±15V Com terminal.
9. Connect the positive lead of the voltmeter to the -15V terminal.
10. If necessary, adjust R25/R57 for a reading of -15 volts ±0.75 volts.
11. Connect the positive lead of the voltmeter to the +15V terminal.
12. If necessary, adjust R26/R82 for a reading of +15 volts ±0.75 volts.
13. When calibration has been completed, replace the column covers.

Airway Pressure Monitor Transducer

The calibration procedure for the Airway Pressure Monitor Transducer is as follows:

1. Locate the pressure transducer ZERO and SPAN screwdriver adjustable controls on the rear panel of the Control Package below the battery compartment (see Figure 4.2). Have a suitably-small screwdriver available to make any necessary adjustments.
2. Attach a digital readout type pressure transducer meter to the bottom “leg” of a 1/8" “T” fitting. Attach one of the “arms” of the “T” fitting directly to the pressure sense fitting of the patient “Y.” Attach the 3100A's 1/8" PVC pressure sense tubing directly to the other “arm” of the “T” fitting.
3. Plug the end of the patient circuit “T” with a #1 rubber stopper. Turn on the bias-flow gas pressure, press reset until the $\overline{P}aw$ comes up, and create a mean pressure of 39-43

cmH_2O (as read on the transducer meter) by using the Mean Pressure and Bias Flow controls (as explained in the Start Up Procedures section of Chapter 4).

4. Remove the #1 stopper and verify that the MEAN PRESSURE display reads –0.5 to +0.5 cmH2O. Adjust the ZERO control on the rear panel until the Mean Pressure display matches the pressure transducer meter reading within ±0.3 cmH_2O. This reading is typically between 0.2 and 0.3 cmH_2O.
5. Replace the #1 stopper, press reset until the $\overline{P_{aw}}$ comes up, and re-establish the 39-43 cmH_2O mean pressure reading on the transducer meter as explained in Step 3, above.
6. Adjust the rear-panel SPAN control until the Mean Pressure Monitor display matches the pressure transducer meter within ±0.3 cmH_2O.
7. If the SPAN control requires no adjustment, the calibration procedure is now complete. But if the SPAN control required readjustment, steps 4,5, and 6 must be repeated (typically twice) until both the near-zero level and the 39-43 cmH_2O levels match within ±0.3cmH_2O.
8. The pressure transducer calibration procedure is now complete.

Piston Position and Displacement Calibration

The calibration procedure for the Piston Position and Displacement display is as follows:

1. Turn off Power to the 3100A and unplug from AC.
2. Remove four screws and slide off Control Package cover.
3. Plug 3100A back into receptacle and turn on Power.
4. Turn on gas supply pressure for Bias Flow only.

Note

Do not *turn on the cooling air.*

5. Leave the ET tube connection of the Patient Circuit open to start, but have a #1 rubber stopper ready for use.
6. Refer to Figure 7.1 to locate screwdriver potentiometers R1, R4, and R7 for the Dynamic Displacement Indicator (DDI) Board within the control package.

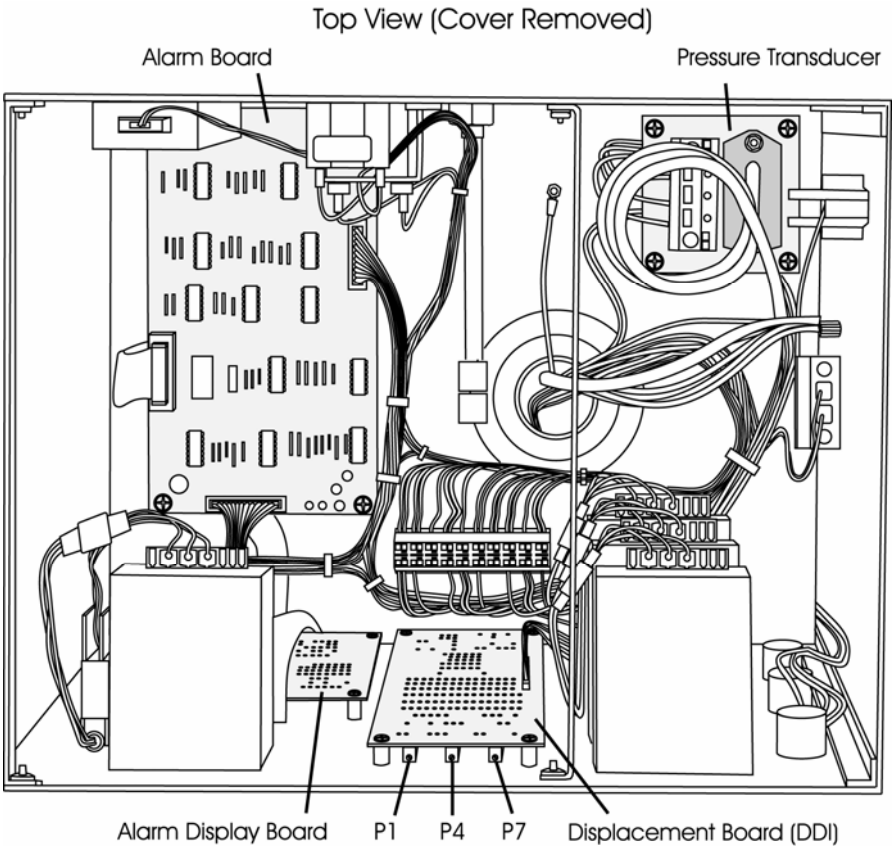


Figure 6.7. Control Package Circuit Boards and Component Layout.

7. Set both Mean Pressure LIMIT and ADJUST controls to Max (full clockwise).
8. Set Bias Flow to 20 LPM.
9. Set the "Set Max $\overline{P_{aw}}$" thumbwheel switch to 00.
10. Make sure the oscillator is disabled.
11. On the DDI board, adjust P7 so that the center segment of the bar graph is lighted.
12. Insert the #1 stopper into the ET tube connection of the patient circuit and observe the Mean Pressure display.
13. The Mean pressure should immediately rise. Note that it settles in the 39-43 cmH_20 range.
14. Adjust P1 to light the far right segment of the bar graph display (segment nearest "Max Exp Limit").

Note

For P7 and P1, a clockwise adjustment will move the lit segment from right to left.

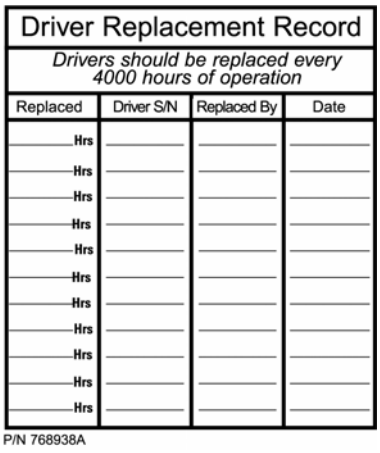
15. Repeat steps 11 through 14 above as many times as required until no further adjustments of P1 or P7 are needed. Always adjust P7 with the stopper out. Always adjust P1 with the stopper in and Mean pressure at 39-43 cmH_2O.
16. Leave the stopper in the ET tube connection.

17. Set Bias Flow to 15 LPM.
18. Set the "Set Max $\overline{Paw}$" thumbwheel above 20.
19. Turn on the gas supply pressure for cooling.
20. Set Frequency to 15, and % I-Time to 33.
21. Depress RESET and establish a Mean airway pressure of 20 cmH_20.
22. With START/STOP, start the oscillator.
23. While observing the ΔP pressure readout, adjust the Power control for a ΔP of 30 and simultaneously center the piston with the Piston Centering control.
24. Adjust P4 on the DDI board so that a total of three segments are lighted on the bar graph.
25. When calibration has been completed, remount the Control Package cover and restore to operating settings.

Scheduled Periodic Maintenance

There are four other scheduled maintenance intervals suggested by SensorMedics, based on accelerated life testing data, clinical usage history and the type of oscillator subassembly installed in your 3100A. These are:

1. Every 4,000 operating hours, have the 1.5 ohm Oscillator Subassembly ("Driver") replaced with a new or rebuilt unit which has new diaphragms and support spiders (the parts subject to flexure fatigue). This replacement must be done by a factory trained technician.


Driver Replacement Record

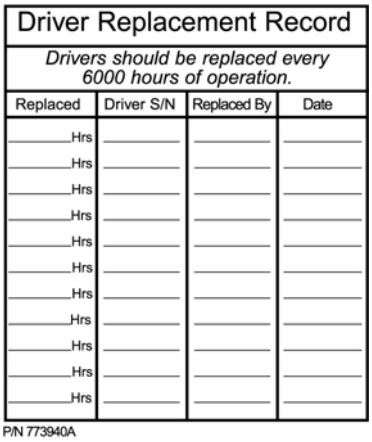
Drivers should be replaced every 4000 hours of operation

Replaced	Driver S/N	Replaced By	Date
_____Hrs			
_____Hrs			
_____Hrs			
_____Hrs			
_____Hrs			
_____Hrs			
_____Hrs			
_____Hrs			
_____Hrs			
_____Hrs			
_____Hrs			

P/N 768938A

Figure 6.8 Driver Record Label 4000 Hours

2. Every 8,000 operating hours, have the 3100A HFOV with a 1.5 ohm driver (oscillator), overhauled by a factory trained technician. This overhaul will include the replacement of the 1.5 ohm driver plus the replacement of all other parts subject to usage wear and aging (e.g., solenoid valves, regulators, plastic tubing, and cooling fans).
3. Every 6,000 operating hours, have the 3.0 ohm driver (oscillator) assembly replaced with a rebuilt unit. Select pneumatic components must also be replaced at this time. This maintenance must be performed by a factory trained technician.



Driver Replacement Record

Drivers should be replaced every 6000 hours of operation.

Replaced	Driver S/N	Replaced By	Date
_____Hrs			
_____Hrs			
_____Hrs			
_____Hrs			
_____Hrs			
_____Hrs			
_____Hrs			
_____Hrs			
_____Hrs			
_____Hrs			
_____Hrs			

P/N 773940A

Figure 6.9 Driver Record Label 6000 Hours

4. Every 12,000 hours, have the 3100A with a 3.0 ohm driver assembly overhauled . This overhaul will include replacement of the 3.0 ohm driver and pneumatic components (i.e. regulators, tubing, fittings and valves). The cooling fan, circuit breaker and thumbwheel switches will also be replaced at this time. This overhaul must be performed by a factory trained technician.

5. Every 7 years, have the Driver Power Module replaced. The Driver Power Module is an assembly consisting of the Driver controller Board, Choke Board, and the Pulse Width Modulator. This maintenance must be performed by a factory trained technician

Troubleshooting

This section is intended to assist the operator in identifying and correcting any apparent malfunctions of the 3100A System. For assistance, please see Appendix A for VIASYS Customer Care contact information and technical support telephone numbers.

Special Environmental Considerations

Excessive amounts of dust and lint in the area around the 3100A can block the cooling fan input at the base of the unit and cause malfunctions. We recommend keeping the instrument environment as clean and well-ventilated as possible, along with the normal maintenance of the cooling fan filter as described earlier in this chapter.

Electrostatic Discharge

The 3100A is designed and tested to withstand normal to high amounts and occurrences of Electrostatic Discharge (ESD). Under certain circumstances, however, it is still possible for ESD to cause component damage to the 3100A. ESD takes place when a person has built up enough static electricity on their body and clothing that a "shock" occurs when they touch something conductive, like metal or another person. This can damage instrument components if the charge is of sufficient strength. To avoid this, especially during conditions of extremely low humidity when the levels of ESD are generally high, touch the outer metal cabinet of the instrument before touching any other component.

Electromagnetic Interference

The 3100A is also designed and tested to withstand normal amounts and occurrences of Electromagnetic Interference (EMI). Under certain circumstances, however, it is possible for EMI to affect the components of the system. EMI consists of electromagnetic waves from one electronic device interfering with the function of another electronic device. These waves can be radiated through the air or conducted through electrical wiring. Likely causes of troublesome EMI in the hospital setting include (but are not limited to) MRI systems, lasers, diathermy equipment, cauterizers, transmitting computers, and hand-held radio transmitters.

Operation of radio transmitters (e.g., walkie-talkies, cellular phones, etc.) within 20 feet of the instrument may cause erroneous pressure readings, which can lead to false alarms and automatic shut-down. These erroneous pressure readings are not due to fluctuations in the actual pressure but are the effect of EMI on the components of the measurement circuits. Once the disturbance stops, the reading returns to normal. If the condition of interference is strong enough, and lasts long enough, the >50cmH_2O or the <20% of Set Max alarms may be triggered, which will cause the dump valve to open and the oscillator to stop. Once the EMI disturbance has stopped or has been removed, press the reset switch to restart the oscillator. The situation can generally be remedied by locating the offending device and then distancing it at least 20 feet away.

In addition to the ***radiated*** EMI described above, ***conducted*** EMI can also cause the same problems by disturbing the AC power line. Typical devices which can exhibit this phenomenon are personal computers and other devices that rely on high speed switching electronics. This sort of interference can be difficult to locate if there are many such devices in the immediate vicinity. Without expensive electronic detection equipment the only means available to locate the offending device is to power down the surrounding systems one at a time until the interference is removed.

It is important to note that ***radiated*** interference from hand-held radio transmitters is the most common, and sources such as these should be isolated first. The majority of devices used in a hospital

environment have been checked for conducted emissions and only through a malfunction of the device is there likely to be an interference problem.

Troubleshooting Chart

The following charts should be used as a guide in correcting problems that may arise in the use of the 3100A. For problems not covered by this list, or for any questions or concerns, call the VIASYS Customer Care Division at the numbers listed in Appendix A

> **CAUTION**
>
> Troubleshooting with the 3100A should always be done ***"OFF PATIENT"*** to avoid any potentially dangerous situations such as abrupt changes in the $\overline{P_{aw}}$.

Table 6.1 Visual / Audible Alarm Occurring

Condition	Possible Causes	Possible Remedies
Displayed $\overline{P_{aw}}$ > 50 cmH2O Alarm	1. Patient at high $\overline{P_{aw}}$ and spontaneously breathing. 2. Obstruction in expiratory limb. 3. Obstruction in pressure sense line. 4. Interference from a radio transmitter.	1. Bias Flow rate possibly insufficient, re-adjust $\overline{P_{aw}}$ using higher flow. Also, consider clinical status of patient. 2. Replace patient circuit. 3. Replace patient circuit. 4. Remove source of interference.
Displayed $\overline{P_{aw}}$ > Set Max $\overline{P_{aw}}$ Thumbwheel Alarm	1. Patient spontaneously breathing. 2. Improper setting of thumbwheel switch. 3. Obstruction in expiratory limb. 4. Obstruction in pressure sense line. 5. Patient circuit temperature rise. 6. Interference from a radio transmitter.	1. Bias Flow rate possibly insufficient, re-adjust $\overline{P_{aw}}$ using higher flow. Also, consider clinical status of patient. 2. Change setting. 3. Replace the patient circuit. 4. Replace the patient circuit. 5. Check and correct circuit temperature. 6. Remove the source of interference.
Displayed $\overline{P_{aw}}$ < Set Min $\overline{P_{aw}}$ Thumbwheel Alarm	1. Patient spontaneously breathing. 2. Improper setting of thumbwheel switch. 3. Improper setting of $\overline{P_{aw}}$ adjust or flowmeter. 4. Patient circuit temperature drop. 5. Improper setting of $\overline{P_{aw}}$ Limit. 6. Leak in patient circuit or humidifier. 7. Cap diaphragm leak. 8. Interference from a radio	1. Bias Flow rate possibly insufficient, re-adjust $\overline{P_{aw}}$ using higher flow. Also, consider clinical status of patient. 2. Change setting. 3. Change setting. 4. Check and correct circuit temperature. 5. Change setting. 6. Eliminate leak or replace circuit. 7. Replace cap diaphragm. 8. Remove source of interference.

Condition	Possible Causes	Possible Remedies
	transmitter.	
Displayed $\overline{Paw}$ < 20 % of Set Max Thumbwheel Alarm	1. Improper setting of thumbwheel switch. 2. Improper setting of $\overline{Paw}$ adjust or flowmeter. 3. Improper setting of $\overline{Paw}$ Limit. 4. Leak in humidifier or patient circuit, including patient disconnect. 5. Cap diaphragm leak. 6. Interference from a radio transmitter. 7. Open Water Trap Stopcock	1. Change setting. 2. Change setting. 3. Change setting. 4. Eliminate leak or replace circuit. 5. Replace cap diaphragm. 6. Remove source of interference. 7. Close Water Trap Stopcock
Oscillator Stopped with no other alarm occurring	1. Power setting too low and ΔP is less than 6 cmH2O. 2. Oscillator not centered. 3. Oscillator Failure.	1. Adjust setting for desired ΔP. 2. Readjust oscillator centering. 3. Call SensorMedics Service.
Source Gas Low Alarm	1. Input pressure less than 30 psi, either from blender or cooling air. 2. Input filter needs replacement. 3. Flow restriction in gas supply lines. 4. Internal leak.	1. Check input gas lines. 2. Replace filters. 3. Replace supply lines. 4. Call SensorMedics Service.
Battery Low Alarm	1. Battery voltage less than optimal. 2. Battery disconnected.	1. Replace battery. 2. Properly reconnect battery.
High pitched alarm. No indicator light	1. The electronics fan stopped.	1. Call SensorMedics service
Oscillator Overheated Alarm	1. No cooling gas flow. 2. Oscillator overheated due to poor cooling gas flow. 3. Oscillator overheated due to mis-centering at extremely high ΔP settings. 4. Oscillator overheated due to mechanical failure of oscillator subsystem.	1. Assure cooling gas supply hose is attached. 2. Check cooling gas flow for blocked filter element or restricted supply hose—replace if necessary. 3. Readjust centering while monitoring $\overline{Paw}$. 4. Call SensorMedics Service.

Table 6.2 Failure During Checkout

Condition	Possible Causes	Possible Remedies
Reset / Power Failure	1. AC power removed from system or main power interruption. 2. Internal power supply failure.	1. Check line cord. If okay, check other equipment on same outlet. If other equipment okay, possible internal fault. Contact SensorMedics Service. 2. To start oscillator after correcting problem, apply power to system, press and hold "RESET" to establish $\overline{P_{aw}}$, and then press Stop/Start switch. 3. Call SensorMedics Service.
Failure to meet Patient Circuit Calibration	1. Leak in patient circuit or humidifier connections. 2. Improper flowmeter setting. 3. Open Water Trap Stopcock 4. Internal leak or maladjustment.	1. Eliminate leak or replace patient circuit. 2. Set flowmeter to 20 LPM, sighting on center of ball. 3. Close Water Trap Stopcock 4. Call SensorMedics Service.
Failure of Ventilator Performance Check—$\overline{P_{aw}}$ out of range (LOW)	1. Incorrect Patient Circuit Calibration. 2. Center of flowmeter ball not used to make 20 LPM adjustment. 3. Incorrect altitude range being used. 4. Oscillator not centered properly. 5. Internal Failure.	1. Perform Patient Circuit Calibration. 2. Adjust flow to center of ball. 3. Use appropriate altitude range for your facility. 4. Center piston properly using centering control. 5. Call SensorMedics Service.
Failure of Ventilator Performance Check—$\overline{P_{aw}}$ out of range (HIGH)	1. Incorrect Patient Circuit Calibration. 2. Center of flowmeter ball not used to make 20 LPM adjustment. 3. Incorrect altitude range being used. 4. Oscillator not centered properly. 5. $\overline{P_{aw}}$ set with $\overline{P_{aw}}$ Limit and not $\overline{P_{aw}}$ Adjust 6. Internal Failure.	1. Perform Patient Circuit Calibration. 2. Adjust flow to center of ball. 3. Use appropriate altitude range for your facility. 4. Center piston properly using centering control. 5. Correct settings. 6. Call SensorMedics Service.

Condition	Possible Causes	Possible Remedies
Failure of Ventilator Performance Check—ΔP out of range (LOW)	1. Bias Flow tubing from humidifier to circuit has been cut to less than 30", or tubing not supplied with patient circuit being used. 2. Oscillator not centered properly. 3. Power not set at 6. 4. Compression characteristics of humidifier allowing ΔP to drop. 5. Internal Failure.	1. Use Bias Flow tubing supplied with circuit and do not shorten. 2. Center piston properly using centering control. 3. Set Power to 6. 4. Bypass humidifier for performance check, then re-attach. 5. Call SensorMedics Service.
Failure of Ventilator Performance Check—ΔP out of range (HIGH)	1. Oscillator not centered. 2. Oscillator not warmed up. 3. Incorrect altitude range being used. 4. Internal Failure.	1. Center piston. 2. Allow Oscillator to warm up for 5 minutes. 3. Use appropriate altitude range for your facility. 4. Call SensorMedics Service.

Table 6.3 Unexplained Operation

Condition	Possible Cause	Possible Remedies
Oscillator shuts down and Dump Valve opens during operation	1. Set Max Thumbwheel set too high. $\overline{P_{aw}}$ > 20% Set Max. 2. Drastic change in $\overline{P_{aw}}$ due to over-aggressive control change using the $\overline{P_{aw}}$ Adjust. 3. ET Tube has become disconnected. 4. Radio Frequency Interference.	1. Reset thumbwheel to lower setting closer to target $\overline{P_{aw}}$. 2. Re-establish $\overline{P_{aw}}$ and make any small adjustments to $\overline{P_{aw}}$ using Flowmeter Adjust. Note: see Clinical Guidelines chapter for minimum flow requirements. 3. Reconnect ET Tube. 4. Locate and distance offending device.
Oscillator will not restart after temporary disconnection (such as for routine suctioning).	1. Set Max Thumbwheel control set too high. 2. To restart oscillator, $\overline{P_{aw}}$ must first be >20% of Set Max, but in order to achieve $\overline{P_{aw}}$ >20% of Set Max, oscillator must be on. 3. Internal failure	1. Reset thumbwheel to lower setting closer to target $\overline{P_{aw}}$. 2. Reduce Max Thumbwheel setting temporarily until oscillator starts. If it still will not start, reduce power and increase $\overline{P_{aw}}$ to target level using flowmeter and $\overline{P_{aw}}$ Control valve—then increase power while keeping $\overline{P_{aw}}$ on target by adjusting flowmeter or $\overline{P_{aw}}$ control valve down. 3. Call SensorMedics Service.

Condition	Possible Cause	Possible Remedies
$\overline{P_{aw}}$ unstable—jumps by 2–3 cmH2O	1. Water collecting at $\overline{P_{aw}}$ Adjust Valve. 2. Patient spontaneously breathing. 3. Worn or defective cap diaphragm. 4. Internal Failure.	1. Adjust circuit height for better draining. 2. Bias Flow rate possibly insufficient; re-adjust $\overline{P_{aw}}$ using higher flow. Also, consider clinical status of patient. 3. Replace cap diaphragms. 4. Call SensorMedics Service.
$\overline{P_{aw}}$ jumping by > 5 cmH2O when trying to adjust with $\overline{P_{aw}}$ Adjust Valve.	1. Worn or improperly seated cap diaphragm. 2. Internal Failure.	1. Replace cap diaphragms. 2. Call SensorMedics Service.
Unable to center	1. Extremely high ΔP 2. Cooling gas leak or blockage. 3. Internal Failure.	1. Normal behavior at extremely high ΔP. 2. Check cooling gas supply and filter cartridge, replace if necessary. 3. Call SensorMedics Service.
Oscillator making a squeaking sound	1. Limit Valve set too low. 2. Cap diaphragm defective.	1. Readjust Limit Valve to slightly higher setting. 2. Replace cap diaphragm.

Appendix A Contact and Ordering Information

Technical Support

For assistance, the VIASYS Customer Care Department at SensorMedics can be reached 24 hours a day, 7 days a week at

1 (800) 520-4368 ext. 8500

Ordering Parts and Supplies

Parts and Supplies can be ordered by calling the SensorMedics Customer Service Department. at 1-800-520-4368 ext. 8600. Your Customer Service Representative can answer questions concerning correct parts, configurations and prices for your ventilator.

Part Number	Description
766895	3100A Patient Circuit Body (Box of 4)
766896	Cap/Diaphragm Set (Box of 4)
766897	Bellows/Watertrap (Box of 4)
767163	Gas Filter Cartridge Element (Package of 10)
765734-104	Connecting Tube Assembly (8" length, blue)
765734-105	Connecting Tube Assembly (8" length, green)
765734-107	Connecting Tube Assembly (36" length, red)
766595	Humidifier Tubing
766798	Column Lint Filter Element
765742	Hold Down Strap, Patient Circuit
463202	Adjustable Cradle, Patient Circuit
768965	Mounting Bracket, Humidifier, 77mm (RCI ConchaTherm)
768968	Mounting Bracket Humidifier, 30mm (Fisher and Paykel)
771375	Flexible Patient Circuit with F & P 730 Heated Wire (Box of 4)
771374	Flexible Patient Circuit with F & P 730 Heated Wire (Box of 4)
480045	Adapter cable for F & P MR600 humidifiers
480044	Adapter cable for F & P MR700 humidifiers
771464	Flexible Patient Circuit with 51" heated wire (for Hudson RCI 380-90 Humidifier) (Box of 4)
771463	Flexible Patient Circuit with 38" heated wire (for Hudson RCI 380-90) (Box of 4)
771466	Flexible Patient Circuit with 51" heated wire (for Hudson RCI 380-88 only) (Box of 4)
771465	Flexible Patient Circuit with 38" heated wire (for Hudson RCI 380-88 and Concha IV) (Box of 4)
773996	Flexible Patient Circuit c 38" heated wire for F & P 850 (box of 4)
773997	Flexible Patient Circuit c 51" heated wire for F & P 850 (box of 4)
466952	Adapter cable for F & P 850 humidifiers

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Appendix B Specifications

Controls

Bias Flow

0–40 liters per minute (LPM) Continuous, 15-turn control.

Resolution: 2.5 LPM.

Accuracy: ±10% of full scale at the following conditions: air or oxygen @ 70°F and 760 Torr.

Mean Pressure Adjust

Approximately 3–45 cmH_2O minimum range; Bias Flow dependent.

Resolution: 0.1 cmH_2O on airway pressure digital meter, 1-turn control.

Accuracy: Non-calibrated control knob.

Mean Pressure Limit

Approximately 10–45 cmH_2O mean proximal airway pressure.

Resolution: 0.1 cmH_2O on airway pressure digital meter, 1-turn control.

Accuracy: Non-calibrated control knob.

Power

At 100% power, ΔP >90 cmH_20 max amplitude of proximal airway pressure.

Resolution: Graduated 10-turn locking dial, not calibrated in % power.

Frequency-Hz

3–15 Hz oscillator frequency.

Resolution: 0.1 Hz on digital meter, 10-turn control.

Accuracy: ±5% of full scale.

% Inspiratory Time

30–50% of oscillatory cycle.

Resolution: +/- 1% as read on digital meter

Accuracy: ±5% of full scale.

Start/Stop

Oscillator enable/disable.

Set Max $\overline{P_{aw}}$ Alarm Thumbwheel

0–49 cmH_2O mean airway pressure.

Resolution: 1 cmH2O

Accuracy: Within ±2 cmH_20.

Set Min $\overline{P_{aw}}$ Alarm Thumbwheel

0–49 cmH_2O mean airway pressure.

Resolution: 1 cmH_2O.

Accuracy: Within ±2 cmH_20.

45 –Sec Silence

Inhibits audible alarm function for 45 seconds (±5 seconds).

Reset

Resets $\overline{P_{aw}}$ >50 cmH_2O and <20% of "Set Max $\overline{P_{aw}}$" alarms if condition has been corrected; always resets power failure alarm.

Piston Centering

10-turn control—applies adjustable electrical counterforce to oscillator coil to overcome the tendency of the mean airway pressure to displace the piston off center—centering effect displayed on Piston Position & Displacement bar graph and is effected by the $\overline{P_{aw}}$ level.

Patient Circuit Calibration

Adjusts maximum mean pressure that can be obtained with a specific Patient Circuit (refer to Chapter 2 for setup procedure).

AC Power

On/off.

Indicators

Oscillator Enabled

Green LED (Light Emitting Diode) on Start/Stop pushbutton.

Oscillator Stopped

Red LED.

45-Sec Silence

Yellow LED on pushbutton.

$P\overline{aw}$ >50 cmH2O

Red LED.

$P\overline{aw}$ <20% of "Set Max $P\overline{aw}$ "

Red LED.

Set Max $P\overline{aw}$ Exceeded

Red LED.

Set Min $P\overline{aw}$ Exceeded

Red LED.

Power Failure

Red LED (Power Failure / Reset Pushbutton).

Oscillator Overheated

Yellow LED.

Battery Low

Yellow LED.

Source Gas Low

Yellow LED.

ΔP

Digital meter readout of ΔP to the nearest cmH_2O.

% Inspired Time

Digital meter readout of set % inspiratory time.

Frequency-Hz

Digital meter readout of set oscillator frequency in Hertz.

Piston Position & Displacement

17-segment bar graph display of oscillator piston travel.

Mean Pressure Monitor

Digital meter readout of mean airway pressure measurement to the nearest tenth of a cmH_2O.

Elapsed Time

Digital readout of hours of power applied to the Model 3100A HFOV to nearest tenth of an hour.

Set Max $\overline{P}aw$

Thumbwheel switch marked in cmH_2O.

Set Min $\overline{P}aw$

Thumbwheel switch marked in cmH_2O.

Alarm (audible)

3khzmodulated tone.

AC Power

Visual indication of AC power applied (I/0).

Pressure Measurement

Range:	–130 to +130 cmH_2O airway pressure.
Resolution:	0.1 cmH_2O.
Accuracy:	Within ±2% of reading or ±2 cmH_2O, whichever is greater, assuming periodic calibration as described in Chapter 6.
Transducer Pressure Limit	20 psig.

WARNING
Failure to comply with the recommended maintenance procedures for the Airway Pressure Monitor as described in Chapter 6 could result in injury to the patient or operator or could result in damage to the equipment.

Alarms

Safety Alarms

Audible and visual indicators, machine intervention.

$\overline{P_{aw}}$ >50 cmH_2O

Indicators activated, oscillator stopped, and dump valve opened when limit exceeded.

Resolution: Preset.

Accuracy: ±2% of pressure monitor reading or ±2 cmH_2O, whichever is greater.

$\overline{P_{aw}}$ >20% of "Set Max $\overline{P_{aw}}$"

Indicators activated, oscillator stopped, and dump valve opened when limit exceeded.

Resolution: Preset to 20% of Set Max $\overline{P_{aw}}$ thumbwheel setting.

Accuracy: ±2% of pressure monitor reading or ±2 cmH_2O, whichever is greater.

Warning Alarms

Audible and visual indicators, operator intervention.

Set Max $\overline{P_{aw}}$ exceeded

Indicators activated when set limit exceeded.

Range: 0–49 cmH_2O.

Resolution: 1 cmH_2O.

Accuracy: ±2% of pressure monitor reading or ±2 cmH_2O, whichever is greater.

Set Min $\overline{Paw}$ exceed

Indicators activated when set limit exceeded.

Range: 0–49 cmH_2O.

Resolution: 1 cmH_2O.

Accuracy: ±2% of pressure monitor reading.

Caution Alarms

Visual alarm, operator intervention.

Oscillator Overheated

Indicator activated when oscillator coil reaches a temperature of 175°C.

Accuracy: ±5%.

Battery Low

Indicator activated when battery which operates power failure alarm is low and must be replaced.

Source Gas Low

Indicator activated when blended gas or oscillator air cooling source pressure drops below 30 psig limit.

Accuracy: ±5% in source gas mode.

45-Second Silence

Indicator activated for 45 seconds when pushbutton pushed.

Accuracy: ±5 seconds.

Power Failure

Audible and visual indicators activated when power switch turned off, power plug unplugged, or insufficient supply voltage within the electronics package.

Oscillator Stopped

Audible and visual indicators activated when patient's airway ΔP falls below 5 to 7 cmH_2O.

WARNING
An audible alarm indicates the existence of a condition potentially harmful to the patient and should not go unattended. Failure to respond to alarms could result in injury (including death) to the patient and/or damage to the ventilator.

Electrical Specifications

Power

115 VAC, 7.5A, 60 Hz
100 VAC, 7.5A, 50 Hz
220 VAC, 4.0A, 50 Hz
240 VAC, 4.0A, 50 Hz.

Leakage Current

<100 Microamperes.

Overload Protection

Dual electromagnetic circuit breaker.

Power Line Connection

3-wire grounded hospital-grade plug.

Safety Standards

Designed to:

CSA C22.2 No.125

UL-544.

ETL Listed (USA and Canada 3100A).

IEC 601-1.

WARNING
Do not attempt to defeat the proper connection of ground wire. This may cause damage to the device or interconnected equipment and could be injurious to patient or to those associated with the device use. This device is factory equipped with a hospital grade AC power plug. Grounding reliability can only be assured when connected to a tested receptacle labeled "Hospital Grade."

Pneumatic Connections

Inlet from Blender (Air/O2)

DISS oxygen fitting.

Pressure Range:	40–60 psig.
Maximum Flow	40 LPM ±10%.
Overpressure Protection	75 psig ±15% relief valve.

Air Cooling Inlet

DISS air fitting.

Pressure Range	40–60 psig.
Flow	15 LPM +/-10% for 1.5 ohm driver assembly
	10 LPM +/- 10% for 3.0 ohm driver assembly
Overpressure Protection	75 psig ±15% relief valve.

Outlet to Humidifier

3/8" barbed fitting.

Overpressure Protection	5 psig ±15% relief valve.

$P\overline{aw}$ Control Valve

Coded green, Luer bulkhead.

$P\overline{aw}$ Limit Valve

Coded blue, Luer bulkhead.

Dump Valve

Coded red, Luer bulkhead.

$P\overline{aw}$ Sensing

Coded white, Luer bulkhead.

Physical Specifications

Materials

All materials used in the construction of the 3100A instrument and its breathing circuit are non-toxic and pose no safety risk to the patient or operator.

Dimensions of Column & Control Package

Height:	53.8"
Width:	18.6"
Depth:	11.4"
Weight:	143 lbs.

Pedestal

5 legs each with 4" diameter locking wheels, 28" width across bottom of pedestal.

> **CAUTION**
>
> Do not place on the control package of the ventilator anything containing fluid, any accessories that weigh more than 10 pounds, or that extend more than six inches above the ventilator electronics package or beyond its sides. This could cause damage to the ventilator, or could cause the ventilator to tip over, resulting in patient or user injuries and/or damage to the equipment.

Required Environmental & Operational Conditions

1. Temperature: 5–40°C
2. Humidity: 15%–95% (non-condensing)
3. Certain specific environmental factors such as Electrostatic Discharge (ESD) and Electromagnetic Interference (EMI) require special consideration by the operator. For an in-depth discussion of these factors, see the Troubleshooting section of Chapter 6, Maintenance and Troubleshooting.

Performance Graphs

Distal Tidal Volume vs. Frequency at Maximum Power

- Two % I-Time Settings
- Single ET Tube Size
- Single Compliance

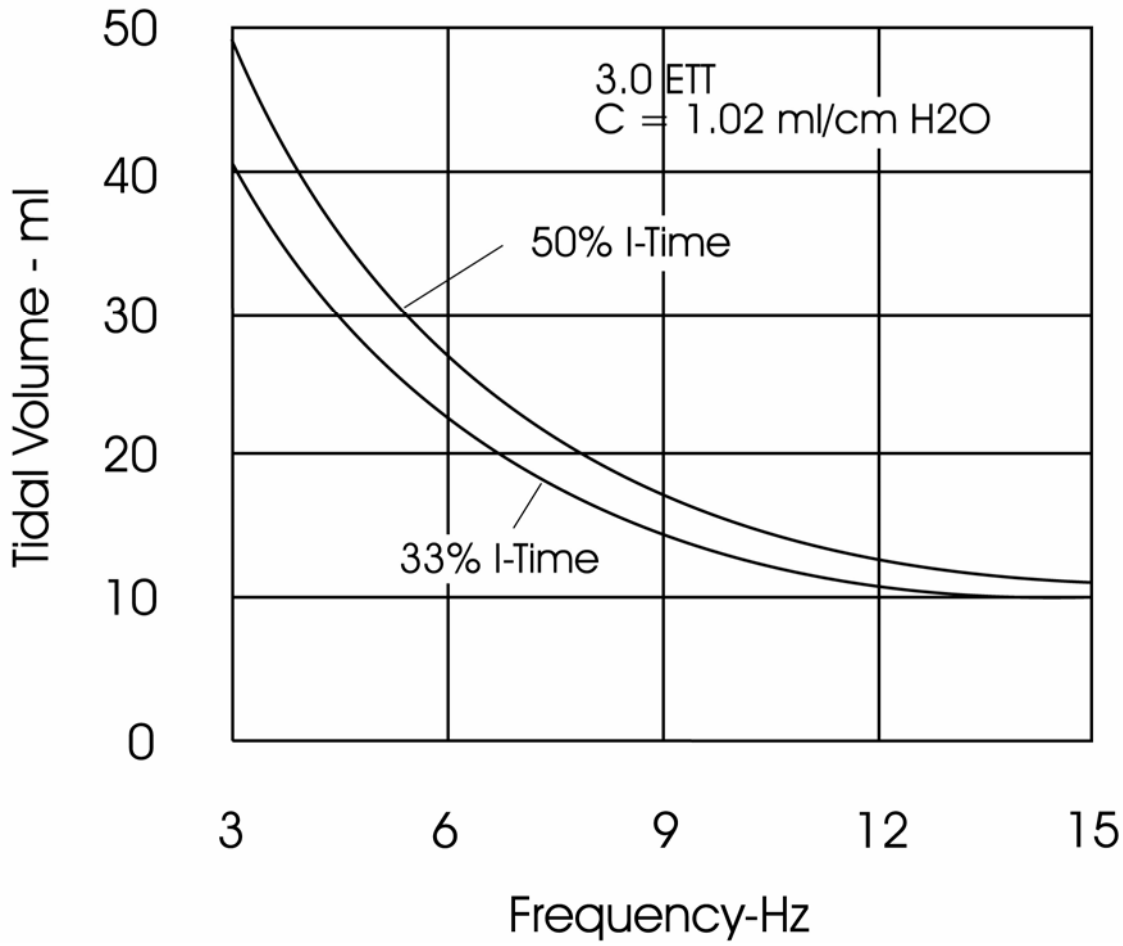

Figure B.1

Distal Tidal Volume vs. Frequency at 15 Hz and 33% I-Time

- Three ET Tube Sizes
- Single Compliance

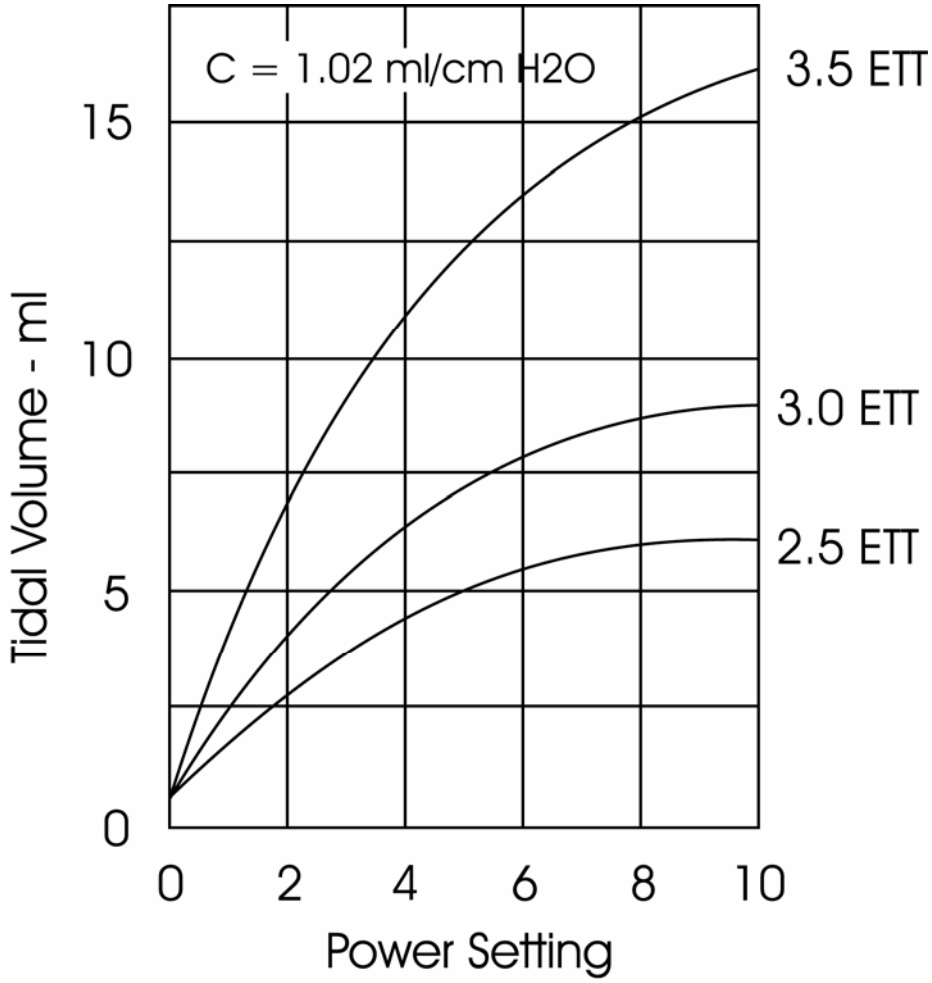

Figure B.2

ΔP Ratio vs. Frequency at Maximum Power and 50% I-Time.

- Three ET Tube Sizes
- Single Compliance

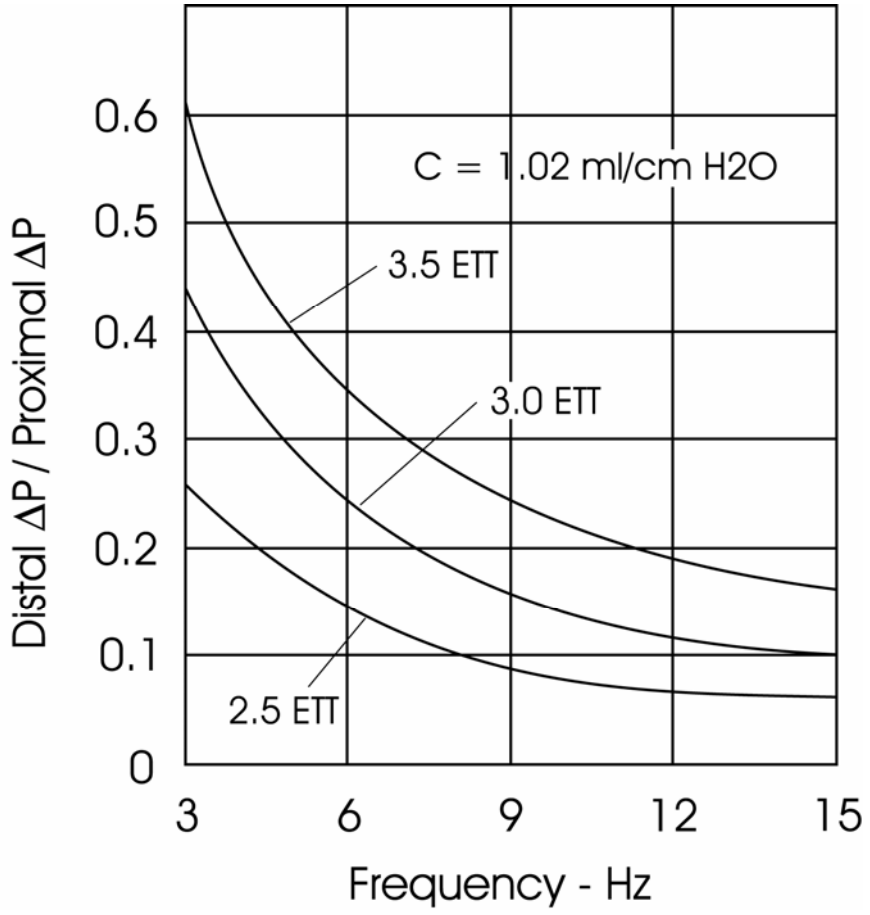

Figure B.3

Distal Tidal Volume vs. Frequency at Maximum Power and 33% I-Time

- Three ET Tube Sizes
- Single Compliance

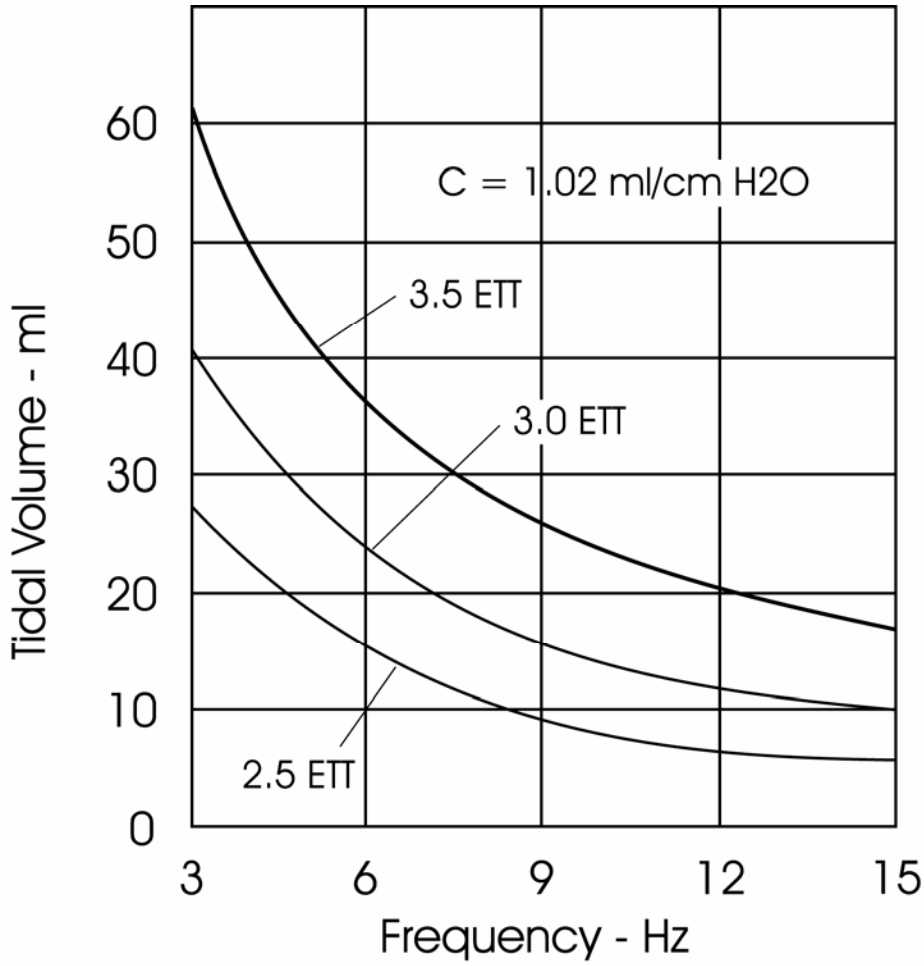

Figure B.4

Distal Tidal Volume vs. Frequency at Maximum Power and 33% I-Time

- Single ET Tube Size
- Three Compliances

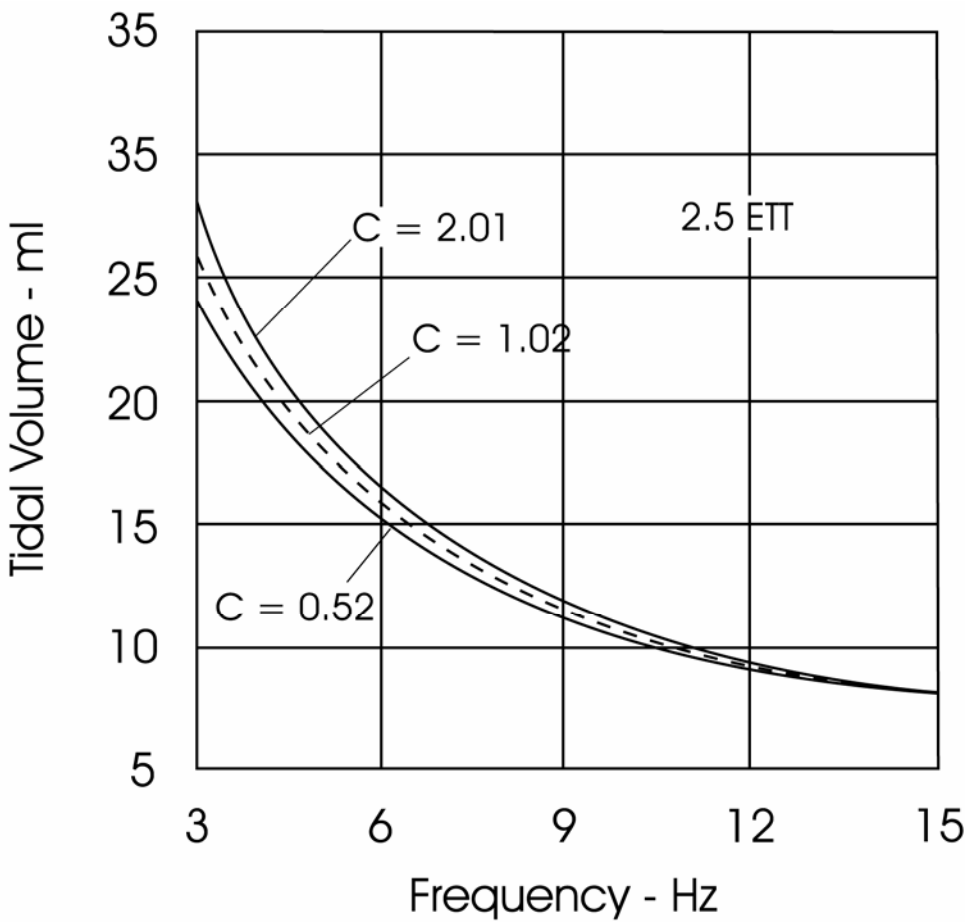

Figure B.5

Distal Tidal Volume vs. Frequency at Maximum Power and 33% I-Time

- Three ET Tube Sizes
- Single Compliance

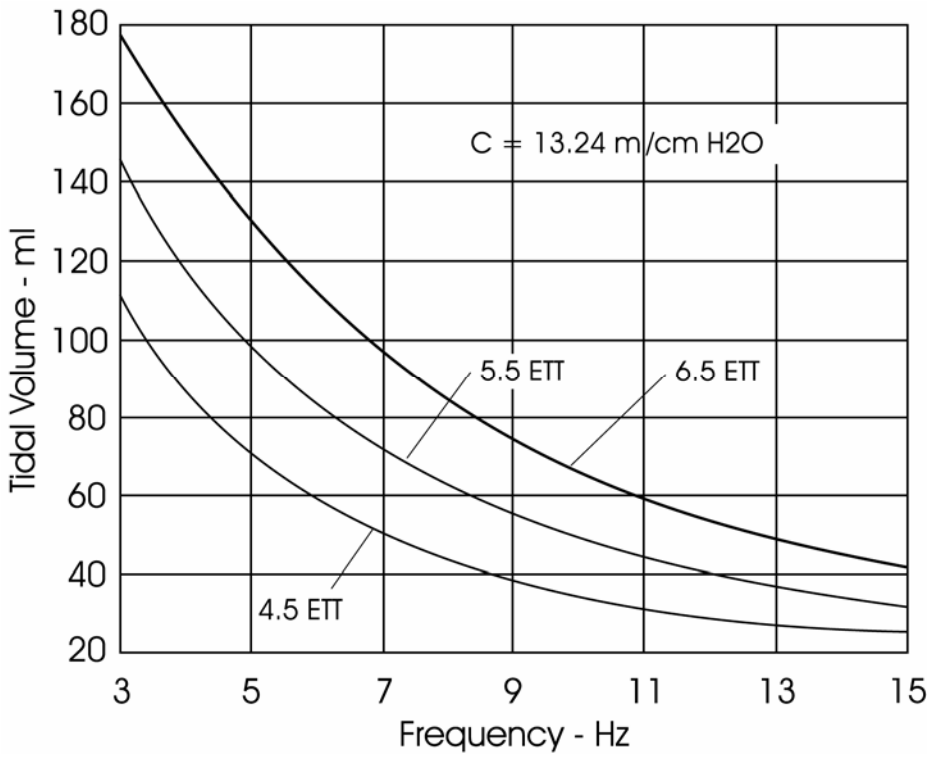

Figure B.6

ΔP Ratio vs. Frequency at Maximum Power and 33% I-Time

- Three ET Tube Sizes
- Single Compliance

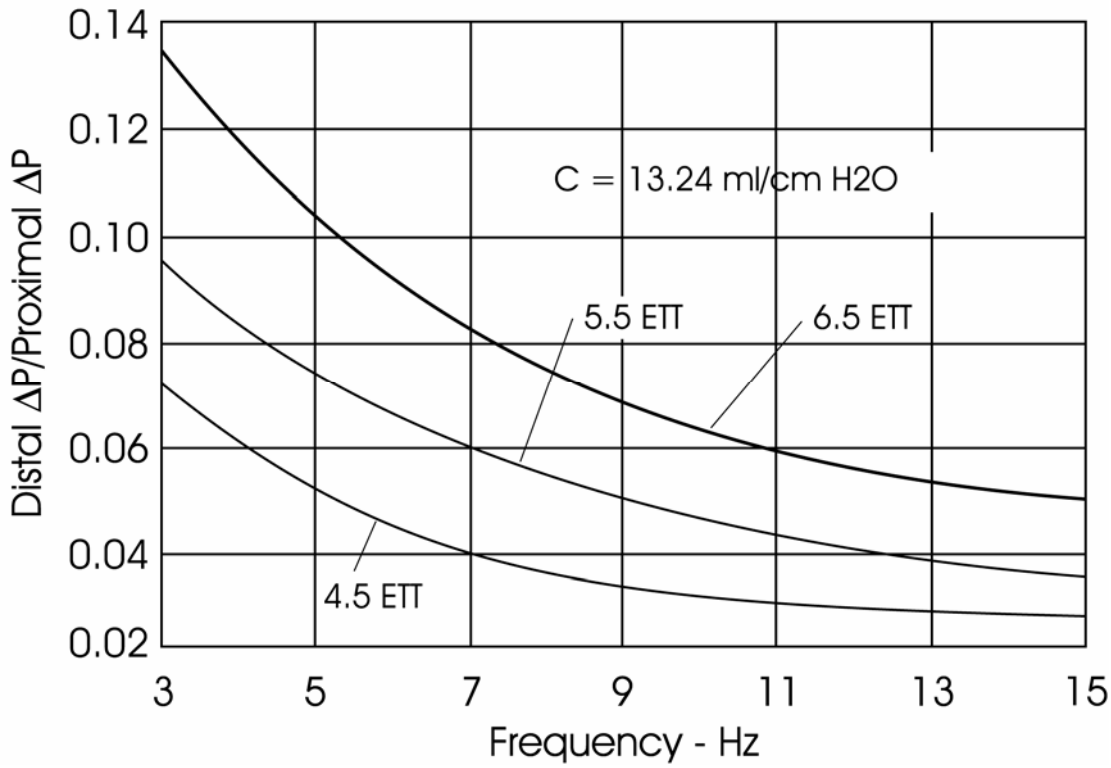

Figure B.7

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